EXHIBIT 1

AO 88A (Rev. 12/20) Subpoena to Testify at a Deposition in a Civil Action

United States District Court

for the

District	of Delaware
Apple Inc. Plaintiff v. Masimo Corporation and Sound United, LLC Defendant)) Civil Action No. 22-cv-1378-MN-JLH)))
	A DEPOSITION IN A CIVIL ACTION
	Sotera, Inc. Suite 140, Carlsbad, CA 92008 to whom this subpoena is directed)
deposition to be taken in this civil action. If you are an or party serving this subpoena about the following matters,	ear at the time, date, and place set forth below to testify at a rganization, you must promptly confer in good faith with the or those set forth in an attachment, and you must designate one nate other persons who consent to testify on your behalf about
Place: TransPerfect Translations 401 B Street, Suite 2320 San Diego, CA 92101	Date and Time: 08/10/2023 10:00 am
The deposition will be recorded by this method:	Stenographically, audiotaped, and videotaped
electronically stored information, or objects, and material:	also bring with you to the deposition the following documents, I must permit inspection, copying, testing, or sampling of the test to be produced on or before July 28, 2023, to: Park Avenue, New York, NY 10169
	re attached – Rule 45(c), relating to the place of compliance; et to a subpoena; and Rule 45(e) and (g), relating to your duty to of not doing so.
Date:07/14/2023 CLERK OF COURT	OR /s/ Jamie L. Kringstein
Signature of Clerk or Deputy	Clerk Attorney's signature
The name, address, e-mail address, and telephone number Plaintiff Apple Inc. Jamie Kringstein Desmarais LLP 230 Park Ave., New Y	er of the attorney representing (name of party), who issues or requests this subpoena, are: York, NY 10169 212-808-2921 jkringstein@desmaraisllp.com

Notice to the person who issues or requests this subpoena

If this subpoena commands the production of documents, electronically stored information, or tangible things before trial, a notice and a copy of the subpoena must be served on each party in this case before it is served on the person to whom it is directed. Fed. R. Civ. P. 45(a)(4).

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Civil Action No. 22-cv-1378-MN-JLH

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 45.)

n (date)	bpoena for (name of individual and title, if an	<u> </u>	
☐ I served the su	abpoena by delivering a copy to the nan	ned individual as follows:	
		on (date) ; or	
☐ I returned the	subpoena unexecuted because:		
tendered to the w	ena was issued on behalf of the United itness the fees for one day's attendance		
y fees are \$	for travel and \$	for services, for a total of \$	0.00
I declare under pe	enalty of perjury that this information is	s true.	
te:			
		Server's signature	
		Printed name and title	
		Server's address	

Additional information regarding attempted service, etc.:

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Federal Rule of Civil Procedure 45 (c), (d), (e), and (g) (Effective 12/1/13)

(c) Place of Compliance.

- (1) For a Trial, Hearing, or Deposition. A subpoena may command a person to attend a trial, hearing, or deposition only as follows:
- (A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or
- **(B)** within the state where the person resides, is employed, or regularly transacts business in person, if the person
 - (i) is a party or a party's officer; or
- (ii) is commanded to attend a trial and would not incur substantial expense.

(2) For Other Discovery. A subpoena may command:

- (A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and
 - (B) inspection of premises at the premises to be inspected.

(d) Protecting a Person Subject to a Subpoena; Enforcement.

(1) Avoiding Undue Burden or Expense; Sanctions. A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.

(2) Command to Produce Materials or Permit Inspection.

- (A) Appearance Not Required. A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.
- **(B)** Objections. A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing, or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:
- (i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.
- (ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

(3) Quashing or Modifying a Subpoena.

- (A) When Required. On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:
 - (i) fails to allow a reasonable time to comply;
- (ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);
- (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
 - (iv) subjects a person to undue burden.
- **(B)** When Permitted. To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:

- (i) disclosing a trade secret or other confidential research, development, or commercial information; or
- (ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.
- (C) Specifying Conditions as an Alternative. In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:
- (i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and
 - (ii) ensures that the subpoenaed person will be reasonably compensated.

(e) Duties in Responding to a Subpoena.

- (1) *Producing Documents or Electronically Stored Information.* These procedures apply to producing documents or electronically stored information:
- (A) Documents. A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.
- **(B)** Form for Producing Electronically Stored Information Not Specified. If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.
- (C) Electronically Stored Information Produced in Only One Form. The person responding need not produce the same electronically stored information in more than one form.
- (D) Inaccessible Electronically Stored Information. The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

(2) Claiming Privilege or Protection.

- (A) Information Withheld. A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:
 - (i) expressly make the claim; and
- (ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.
- (B) Information Produced. If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.

(g) Contempt.

The court for the district where compliance is required—and also, after a motion is transferred, the issuing court—may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

For access to subpoena materials, see Fed. R. Civ. P. 45(a) Committee Note (2013).

ATTACHMENT A

SCHEDULE A

DEFINITIONS

The following terms shall have the meanings set forth below whenever used in any Definition, Instruction, Request for Production, or Deposition Topic.

- 1. As used herein, the terms "Sotera," "You," or "Your" means Sotera, Inc., Sotera Wireless, Inc., and all of their predecessors (merged, acquired, or otherwise), successors, subsidiaries, divisions, departments, and affiliates thereof, and all officers, directors, principals, agents, employees, attorneys, and other persons acting on their behalf.
- 2. As used herein, "Apple" means Apple Inc., all of its predecessors (merged, acquired, or otherwise), successors, subsidiaries, divisions, departments, and affiliates thereof, and all officers, directors, principals, agents, employees, attorneys, and other persons acting on their behalf.
- 3. As used herein, "Masimo" means Masimo Corporation, Cercacor Laboratories, Inc., and all their predecessors (merged, acquired, or otherwise), successors, subsidiaries, parents, sisters, divisions, departments, partnerships, and affiliates thereof, and all of their officers, directors, principals, agents, employees, independent contractors working under their control, attorneys, and other persons acting on their behalf.
- 4. As used herein, "Masimo Asserted Patents" means U.S. Patent No. 10,687,743 ("the '743 Patent"), U.S. Patent No. 10,722,159 ("the '159 Patent"), U.S. Patent No. 8,190,223 ("the '223 Patent"), U.S. Patent No. 10,736,507 ("the '507 Patent"), and U.S. Patent No. 10,984,911 ("the '911 Patent").
 - 5. As used herein, "Relevant Date" means September 20, 2012.
 - 6. As used herein, "Exhibits" means Exhibits 1-3 attached hereto.

- 7. As used herein, "Blood Oxygen and Heart Rate Features" means the product feature(s) relating to monitoring, measuring, sensing, detecting, and/or obtaining blood oxygen (SpO2) and/or heart rate measurements, including all hardware, software, firmware, components, modules, applications, and devices involved in such features, that were made or sold before the Relevant Date.
- 8. As used herein, "Product" means any machine, manufacture, apparatus, device, system, process, service, method, or instrumentality which is designed to function together electrically, mechanically, chemically, or otherwise, to achieve a particular function or purpose, including those offered for sale, sold, imported, or under development.
- 9. As used herein, "Relevant Products" means (1) the Sotera ViSi Mobile Monitoring System, (2) the ViSi Mobile Monitor, (3) the ViSi Mobile Thumb Sensor, (4) the ViSi Mobile Cuff Module, (5) the ViSi Mobile Chest Sensor Cable, (6) the ViSi Mobile Wrist Strap, (7) the ViSi Mobile Wrist Cradle, (8) any Sotera ViSi Mobile Software, (9) any ViSi Mobile Remote Viewer software, (10) the products described in Exhibits 1-3, (11) any Product made or sold by or for You having Blood Oxygen and Heart Rate Features before the Relevant Date, (12) any related Products or modules having Blood Oxygen and Heart Rate Features before the Relevant Date, and (13) any other software programs, applications, or modules that display Blood Oxygen or Heart Rate from the Relevant Products.
- 10. As used herein, "Source Code" means any human-readable programming language or format that defines software, firmware or integrated circuits, including but not limited to, computer code, scripts, assembly, binaries, object code, Register Transfer Level ("RTL") descriptions, VHDL, Verilog, and other Hardware Description Language ("HDL") formats.

- 11. The term "Third Party" means any person or entity other than You, Masimo, or Apple.
- 12. As used herein, the term "document" shall have the full meaning ascribed to it by the Federal Rules of Civil Procedure and includes the original and every non-identical copy or reproduction in Your possession, custody, or control, and further is used in a broad sense to refer to any electronically stored information ("ESI") or any tangible object or thing that contains, conveys, or records information.
- 13. As used herein, the singular of any word shall include the plural, and the plural shall include the singular.
- 14. As used herein, "person" means any natural person or any business, legal, or governmental entity or association.
- 15. As used herein, "include" and "including" shall be construed to mean "without limitation," so as to give the broadest possible meaning to interrogatories and definitions containing those words.
- 16. As used herein, "and" and "or" shall be construed conjunctively and disjunctively so as to acquire the broadest meaning possible.
- 17. As used herein, "any" and "all" shall each be construed to mean "each and every," so as to acquire the broadest meaning possible.
- 18. As used herein, the singular of any word shall include the plural, and the plural shall include the singular.
- 19. As used herein, "related" or "relating" to any given subject means, without limitation, identifying, describing, discussing, concerning, assessing, stating, reflecting

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constituting, containing, embodying, tending to support or refute, or referring directly or indirectly to, in any way, the particular subject matter identified.

- 20. As used herein, "identify" as applied to a document shall mean to specify: (a) the type of the document (i.e., whether it is a letter, memorandum, e-mail, etc.); (b) the document's title and general subject matter; (c) the number of pages of the document; (d) the date the document was prepared; (e) the name of each and every author, addressee, distributor, and recipient of the document; (f) the date each distributor distributed the document and the date each recipient received the document; and (g) the name of each person that has or had possession, custody, or control of the document.
- 21. Any term not specifically defined herein shall be defined in accordance with normal usage as well as with the Federal Rules of Civil Procedure and the Local Rules of the United States District Court for the District of Delaware.

INSTRUCTIONS FOR REQUESTS FOR PRODUCTION

- 1. Apple's Requests for Production seek responsive documents and information sufficient to answer each of the Requests that are known or available You or in Your possession, custody, or control. If, after exercising due diligence to secure the documents or information requested, You cannot fully respond to a Request for Production, state that such is the case and answer to the fullest extent possible, stating what responsive documents or information are available, what documents or information cannot be provided, why the documents or information are unavailable, and what efforts were made to obtain the unavailable documents or information. If documents or information responsive to a Request in this subpoena are in Your control, but not in Your possession or custody, promptly identify the entity with possession or custody.
- 2. Regardless of whether a production is in electronic or paper format, documents that were maintained together before production should be produced in the same form, sequence, organization, or other order or layout as they were maintained, including any labels, file folders, file jackets, covers, or containers in which such documents are located or with which such documents are associated. If copies of documents are produced in lieu of the originals, such copies should be legible and bound or stapled in the same manner as the original.
- 3. These Requests for Production shall be deemed continuing. Documents located, and information learned or acquired, at any time after Your response is due must be promptly supplemented at the place specified in this subpoena.
- 4. A copy of the Protective Order entered in this Action for the protection of any requested proprietary, confidential, or commercially sensitive information is attached hereto.

REQUESTS FOR PRODUCTION

- 1. Documents sufficient to identify and describe the functionality, features, and operation of the Blood Oxygen and Heart Rate Features of the Relevant Products and all components, modules, applications, hardware, software, and firmware contained therein, including, without limitation, user manuals, brochures, presentations, user guides, product literature, engineering specifications, circuit diagrams, architectural diagrams, bills of materials, technical manuals, product specifications, data sheets, laboratory notebooks, research papers, test data and results, analyses, invention disclosure forms, reports, service manuals, operator's manuals, implementation guides, white papers, product tutorials, and non-public documentation.
- 2. Documents sufficient to identify and describe the conception, design, research, development, testing, use, operation, maintenance, marketing, modifying, sale, offer for sale, and supply of the Relevant Products, including the persons and entities involved.
- 3. Documents, communications, and things comparing the Apple Watch to the Relevant Products.
 - 4. Other versions of the Exhibits and documentation related to the Exhibits.
- 5. Documents sufficient to show the earliest dates that each of the Relevant Products were first conceived; reduced to practice; and made, sold, used (including by third parties such as end users), offered for sale, in public use, and otherwise available to the public in the United States, including but not limited to documents relating to any conference, seminar, exhibition, convention, or trade show at which such Product is or was discussed, referred to, advertised, displayed, demonstrated, or shown, such as, without limitation, product specifications, catalogs, announcements, advertisements, brochures, articles, pamphlets, price lists, invoices, purchase orders, sales records, or other promotional, marketing, or sales materials.
 - 6. Publications related to the Relevant Products that were made available to the public.

- 7. Three samples of each Relevant Product.
- 8. Source Code sufficient to show the functionality of the Blood Oxygen and Heart Rate Features of the Relevant Products.
- 9. Documents relating to any contention by Masimo that any Relevant Product meets any claim of any Masimo patent, including but not limited to Masimo's infringement contentions for U.S. Patent Nos. 9,788,735, 9,795,300, 9,872,623, 10,213,108, and 10,255,994 in *Masimo Corporation v. Sotera Wireless, Inc., et al.*, 19-cv-1100-BAS-NLS (S.D. Cal. 2020).
- 10. Documents sufficient to show the authorship and authenticity of all the documents produced in response to this subpoena.

DEPOSITION TOPICS

- 1. The functionality, features, and operation of the Blood Oxygen and Heart Rate Features of the Relevant Products.
- 2. The earliest dates that each Relevant Product was reduced to practice, made, sold, offered for sale, in public use, or otherwise available to the public.
- 3. The subject matter contained within the documents produced in response to Requests For Production herein, including the authentication thereof.
- 4. The authorship and authenticity of the documents produced in response to the Requests For Production herein.

EXHIBIT 1





ViSi Mobile[®] is a comprehensive monitoring system, designed to enhance patient safety, allowing early detection of patient deterioration and connecting clinicians with their patients anywhere, any time.



Refer to the ViSi Mobile User Documentation [REF: 95-10134]

for Indications for Use, Contraindications, Warnings, Precautions, Description, Set-up, and Operation.

PATIENT-WORN DEVICES		SPECIFICATIONS	
VISI MOBILE MONITOR [REF 92-10010]	Dimensions 2.6 cm H x 4.9 cm W x 9.4 cm L 1.0 in H x 1.9 in W x 3.7 in L Monitor / Display OLED, 160 x 128 pixels, full color, capacitive touch screen Waveforms One waveform, user selectable (ECG, Pleth, Resp) Battery Battery Type Li-Ion, 3.7 V., 2000 mAh, single cell Operating Time 12-24 hours (depending on use profile) Charge Time Less than 4 hours Liquid Ingress Rating: IPX7	Weight 110 g 3.9 oz Audio: Alarm annunciation (72dBA), QRS beep, Self-Test Wireless Connectivity Network Standard: IEEE 802.11b, 11 and 5.5 Mbps Antenna Gain: 1.0 dB Traffic generated (one Monitor): Less than 20 KBps (Numerics, Trends, Events, Waveforms) Wireless Network Security Support: WPA2-PSK Network Protocol: TCP/IP	
VISI MOBILE CUFF MODULE	Dimensions 3.1 cm H x 4.9 cm W x 12.2 cm L 1.2 in H x 1.9 in W x 4.8 in L Display Eight LEDs: Six Green, One Yellow, One Red LEDs in array showing charge levels of onboard battery Battery Battery Type Li-lon, 3.7 V., 2000 mAh, single cell > 30 cuff inflations Charge Time Less than 4 hours	Weight 157 g 5.5 oz Audio None	
VISI MOBILE CHEST SENSOR 3-lead [REF 93-10014] 5-lead[REF 93-10012]	Dimensions 152.4 cm L 60.0 in L Liquid Ingress Rating: IPX7	Weight 3-LEAD WIRE 72 g 62 g 2.5 oz 2.2 oz	
VISI MOBILE THUMB SENSOR [REF 92-10020]	Dimensions 22.5 cm L 8.9 in L Liquid Ingress Rating: IPX7	Weight 8 g 0.3 oz	
Accessories		SPECIFICATIONS	
VISI MOBILE BATTERY CHARGER [8 POSITION] [REF 92-10023]	Charges up to eight ViSi Mobile Monitors / Cuff Modules Dimensions 7.6 cm H x 6.0 cm W x 47.0 cm L 3.0 in H x 2.4 in. W x 18.5 in L (exclusive of power supply & cable) Power Input: AC Adapter, Input: 100-240V, 50-60Hz Liquid Ingress Rating: IPX0	Weight 670 g 1lb 7 oz (exclusive of power supply & cable)	

Accessories		S PECIFICATIONS		
VISI MOBILE BATTERY CHARGER [2 POSITION] [REF 92-10022]	Charges up to two ViSi Mobile Monitors / Cuff Modules Dimensions 7.6 cm H x 6.0 cm W x 12.7 cm L 3.0 in H x 2.4 in W x 5.0 in L (exclusive of power supply & cable) Power Input: AC Adapter, Input: 100-240V 50-60Hz Liquid Ingress Rating: IPX0	Weight 240 g 8.3 oz (exclusive of power supply & cable)		
MODE PLUGS	Plug into ViSi Mobile Monitor to: Turn device off completely: Shipping Plug [REF: 99-10025] Secure Monitor into Wrist Cradle when not using Thumb Sensor, e.g. monitoring ECG only: Locking Plug [REF 99-10026]			
	Contains all disposable components to set-up one individual patient, interchangeable left or right arm Kit Components	Sizing: Relevant to the Blood Pressure Cuff and the Wrist Cradle strap. All other components are one-size-fits-all. Wrist Strap Sizes - Wrist Circumference Ranges		
VISI MOBILE PATIENT KIT (DISPOSABLE)	Wrist Cradle incl. strap – holds ViSi Mobile Monitor on patient's wrist	Small	4 ½-6 in.	11.4-15.2 cm
(2.0)	·	Medium	5-7 in.	12.7-17.8 cm
Satup	Thumb Cradle – holds ViSi Mobile Thumb Sensor on patient's thumb	Large	6-10 in.	15.2-25.4 cm
AC B	Welch Allyn Flexiport [™] Disposable Blood Pressure Cuff – with ViSi Mobile Cuff Module adaptor	Blood Pressure Cuffs Sizes - Arm Circumference Range. (follows Welch Allyn FlexiPort TM cuff sizing)		
[S: REF 92-10066] [M: REF 92-10067]	Cable Securement packet – secures Chest Sensor modules to patient (chest and upper arm)	Small (10)	7.9-10.2 in.	20-26 cm
[M+: REF 92-10070] [L: REF 92-10068] [L+: REF 92-10069	Five (5) Pre-Packaged 3M Disposable ECG Electrodes	Medium (11)	9.8-13.4 in.	25-34 cm
[LT. NEI 92-10009		Medium+ (11L)	9.8-13.4 in.	25-34 cm
		Large (12)	12.6-16.9 in.	32-43 cm
/ITAL SIGNS MEAS	LIDEMENTS	SPECIFICATIONS	12.6-16.9 in.	32-43 cm
ECG HEART RATE	Display Range: 0 to 240 BPM Resolution: 1 BPM Pacemaker: Detects and rejects pacemaker impulses in accordance with ANSI/AAMI EC13:2002 - Displays pacer markers on ECG waveforms Sampling: 500Hz sampling, 19bit resolution Defibrillation Response / Protection - Displays an ECG waveform < 10 seconds after a defibrillation event - Displays HR measurement < 30 seconds after a defibrillation event	Accuracy Range: 30 to 240 BPM Accuracy: 3BPM ±3% of reading Heart Rate Averaging: 10 second moving average 3-Lead: Lead II 5-Lead: Leads I, II, III, aVR, aVL, aVF, and a V lead Factory default alarm threshold: High 200 BPM / Low 30 BPM Audio Alarm Delay: 1 sec		
RESPIRATION	Method: Impedance Pneumography Display Range: 0 to 50 BR/MIN Resolution: 1 BR/MIN	Accuracy Range: 3 to 50 BR/MIN Accuracy: ±3 BR/MIN or 10% of reading, whichever is greater Factory default alarm threshold: High 40 / Low 4 Audio Alarm Delay: 60 seconds on care unit alarm limits, 120 seconds on patient alarm limits		

VITAL SIGNS MEAS	SUREMENTS		SPECIFICATIONS	
Pulse Oximetry (SPO2, Pulse Rate)	SpO2 Display Range: 49 to 100% Accuracy Range: 70 to 100% Accuracy (no motion): ≤ 2% to 100% Resolution: 1% Averaging: Adaptive 30 secon Factory default alarm thresh Audio Alarm delay: 30 secon	ond moving average and:	Pulse Rate (from Oximetry) Display Range: 0 to 240 BPM Accuracy Range: 30 to 240 BPM Accuracy: ± 3 BPM; < 50 BPM @ ≥ 0.6% Puls Modulation / ≥ 50 BPM @ ≥ 0.4% Pulsatile I Resolution: 1BPM Averaging: Adaptive 30 second moving ave Factory default alarm threshold: High 200 / Audio Alarm delay: 30 seconds	
Non-Invasive Blood Pressure (NIBP)	NIBP Method: Oscillometry Accuracy & Display Range: 6 to 160 mmHg (DIA), 50 to 18 Accuracy: Mean error of less standard deviation of ≤ 8 mr Resolution: 1 mmHg Mode of Operation Manual mode – Single NIBP, Automatic mode – NIBP take 5, 10, 15, 30, 60, 90 or 120 n	35 mmHg (MAP) 5 than ± 5 mmHg and a mHg max. 3 tries en automatically every	Pulse Rate (from Oscillometry) Display Range: 0 to 240 BPM Accuracy Range: 30 to 240 BPM Accuracy: ± 3 BPM; < 50 BPM @ ≥ 0.6% Pulsati Modulation / ≥ 50 BPM @ ≥ 0.4% Pulsatile Mo Resolution: 1BPM	
CONTINUOUS NON- INVASIVE BLOOD PRESSURE (CNIBP)	cNIBP Method: Based on Pulse Arri Accuracy & Display Range: 6 to 160 mmHg (DIA), 50 to 18 Accuracy: Mean error of less standard deviation of ≤ 8 mr Resolution: 1 mmHg Averaging: 60 seconds Mode of Operation Initial calibration required w Module	of to 240 mmHg (SYS), 40 35 mmHg (MAP) than ± 5 mmHg and a mHg		
	^O Centigrade		^O Fahrenheit	
TEMPERATURE (SKIN)	Accuracy Range 0.0° - 19.9° 20.0° - 24.9°	Accuracy ±0.3° ±0.3°	Accuracy Range 32.0° - 67.9° 68.0° - 76.9°	Accuracy ±0.5° ±0.5°
(at 102 kPa / 768 mmHg atmospheric pressure)	25.0° - 35.9° 36.0° - 39.9° 40.0° - 41.9° 42.0° - 50.0°	±0.2° ±0.1° ±0.2° ±0.3°	77.0° - 96.7° 96.8° - 103.9° 104.0° - 107.5° 107.6° - 122.0°	±0.3° ±0.2° ±0.3° ±0.5°
	Resolution: ± 0.1° Transient Response: < 6 min	n (25.0° – 37.0°)	Resolution: ± 0.1° Transient Response: < 6 min	(77.0° - 98.6°)

SYSTEM COMPONENTS [ALL SYSTEM COMPONENTS ARE PROVIDED, IMPLEMENTED AND CONFIGURED BY SOTERA WIRELESS]

Standard Server Configuration

Single 1u, redundant hardware and internal RAID 10, dedicated hardware

Processor: Single Intel Xeon 5620, 2.4 GHz, (or equivalent CPU), 8GB memory

Storage: Server contains (4) 500GB 7200 RPM Hard drives in RAID 10 array

Operating System

SUSE Linux Enterprise Server 11 Service Pack 2

Network Requirements

Static IP address or DHCP reservation required Multicast configuration on network backbone

devices

APPLIANCE

Dimensions (single appliance, may vary):

4.3 cm H x 43.4 cm W x 62.7 L cm (w/o ear, w/o bezel)

1.7 in H x 17.1 in W x 24.7 L

Weight (single appliance): 35.0 lbs (15.9 kg)

[Maximum configuration weight]

Power Requirements (single appliance): w/Redundant Power supply 100-240 VAC, 50-60 Hz, 7A-3.5A Backup Power Requirement (full system): Customer supplied Uninterruptable Power Supply required, Hospital Emergency Power recommended

*** This configuration is only recommended for systems of less than 32 ViSi Mobile Monitors, and if high-availability is not required and downtime for SW update is acceptable High-Availability Server Configuration

Dual 1u load balanced, redundant hardware and external SAN in RAID 10 configuration, dedicated hardware.

Processor:

Single Intel Xeon 4 core E5620, 2.4 GHz (or equivalent CPU) in each server, 8GB memory

Storage:

Each Server in the cluster contains (1) 500 GB 7200 RPM Hard Drive to support the operating system SAN: 2u chassis houses (6) 1TB 7200 RPM hard drives in RAID 10 configuration, connected to both servers via

iSCSI, can be expanded Operating System

SUSE Linux Enterprise Server 11 patch 2

Network Requirements

Static IP address or DHCP reservation required Multicast configuration on network backbone devices Dimensions (single appliance, may vary):

4.3 cm H x 43.4 cm W x 62.7 cm L (w/o ear, w/o bezel) 1.7 in H x 17.1 in W x 24.7 L

Weight (single appliance): 35.0 lbs (15.9 kg)

[Maximum configuration weight]

Power Requirements (single appliance): w/Redundant

Power supply 100-240 VAC, 50-60 Hz, 7A

Backup Power Requirement (full system): Customer supplied dual Uninterruptable Power Supply required,

Hospital Emergency Power recommended

SAN Dimensions (may vary):

8.7 cm H x 43.4 cm W x 62.7 cm L 3.4 in H x 17.6 in W x 20.0 in L

SAN Weight (may vary): 53.4 lbs (24.2 kg)

[Maximum configuration weight]

SAN Power Requirements: 100-240 VAC, 50-60 Hz, 5.5A

Future Release. Appliance sizing and drive configuration depends on number of ViSi Mobile Monitors and the length of time the healthcare facility is required to retain vital sign data.

^{**} The high availability configuration minimizes unplanned downtime due to hardware failures and supports live service while periodic application upgrades occur.

Recommended

Desktop PC - Touchscreen Display

All-in-One configuration

Patients per Remote Viewer: Max. 32

Display: 23-inch display, 1920x1080 resolution (screen is touch sensitive to issue commands alternative to mouse /

keyboard) Processor

Intel i5 2400 CPU 4 Core, 3.10GHz, 4Gb Memory

Storage

REMOTE VIEWER (STATIONARY)

One 500GB 7200RPM SATA

Operating System:

Windows 7 Professional x64 Bit SP1

Network Requirements: Ethernet Connection, DHCP

Dimensions:

45.0 cm H x 58.5 cm W x 10.3 cm D 17.7 in H x 23.0 in W x 4.1 in D Weight: 26.7 lb (12.1 kg)

Power Requirements: AC/DC Adapter, Input: 100-240V~3.5A, 50-60Hz, Output to Viewer: 19.5V/ 11.8A Backup Power Requirement: Customer supplied Uninterruptable Power Supply and Hospital

Emergency Power recommended

Alternate

Desktop PC - Standard Display (not touch sensitive)

All-in-One configuration

Patients per Remote Viewer: Max. 32

Display: 23-inch display, 1920x1080 resolution (screen is not touch sensitive and commands are issued using a mouse / keyboard)

Processor

Intel i5 2400s CPU 4 Core, 2.5GHz, 4Gb Memory

Storage

One 500GB 7200RPM SATA

Operating System: Windows 7 Professional x64 Bit SP1
Network Requirements: Ethernet Connection, DHCP

Dimensions:

47.2 cm H x 58.4 cm W x 22.0cm D 18.6 in H x 23.0 in W x 8.7 in D Weight: 18.7 lb (8.5 kg)

Power Requirements: AC/DC Adapter, Input: 100-240V~2A, 50-60Hz, Output to Viewer: 19V / 7.9A Backup Power Requirement: Customer supplied Uninterruptable Power Supply and Hospital Emergency

Power recommended

CUSTOMER NETWORK [Network to be implemented and managed by end user in accordance with IEC 80001-1]

Wireless Network

Wireless Network Standard: IEEE 802.11b

Network latency: <150ms

Wireless Network Security Support: WPA2-PSK Minimum Receiver Sensitivity: -65dBm (edge

coverage)

Wireless access point cell overlap: 15-20%

Signal-to-Noise Ratio: ≥ 25 db

Packet loss: ≤6%

SSID: Dedicated or shared with other medical devices

Wired Network

Appliance (Server): requires Static IP Address

Network availability: >99.99%

AGENCY COMPLIANCE

ANSI/AAMI:

Cardiac monitors, heart rate meters, and alarms EC53, ECG cables and lead wires.

ISO:

9919, Medical electrical equipment - Particular requirements for the basic safety and essential performance of pulse oximetry equipment for medical use.

81060-2, Non-invasive sphygmomanometers - Part 2: Clinical validation of automated measurement type.

IFC

60601-1, Medical electrical equipment - Part 1: General requirements for safety

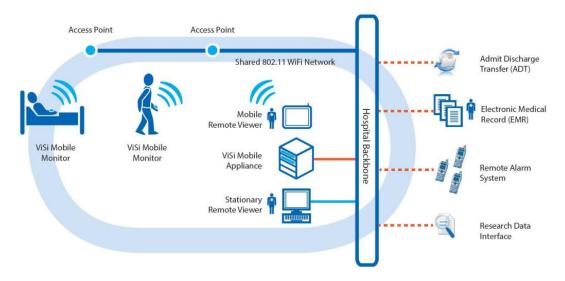
60601-1-2, Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: EMC–Req. and tests.

60601-1-8, Medical electrical equipment – Part 1-8: General requirements – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems.

60601-2-27, Medical electrical equipment - Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment.60601-2-49, Particular requirements for the safety of multifunction patient monitoring equipment.

80601-2-30, Medical electrical equipment – Part 2-30: particular requirements for the safety, including essential performance, of auto-cycling NIBP monitoring equipment.

VISI MOBILE SYSTEM ARCHITECTURE



The ViSi Mobile System has received CE mark and is currently FDA cleared for continuous monitoring of ECG, Heart/Pulse Rate, SpO₂, Blood Pressure (cuff-based and cuffless on a beat-to-beat basis), Respiration Rate and Skin Temperature. Posture/Activity is in final stages of development and is not yet cleared.

For questions please call +1 (866) 794-5526 (from US) or +1 (858) 373-4870 (from intl.), email Support@SoteraWireless.com or visit www.SoteraWireless.com



EXHIBIT 2



Monitoring System

Technical Reference Manual

July 2015

Reference Number (USB): 95-10134

Part Number: 6-000147-06

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For additional information or assistance, please contact Sotera Wireless, Inc. or an authorized Sotera Wireless, Inc. representative in your area.

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Information for servicing the ViSi Mobile Monitoring System is contained in the ViSi Mobile Monitoring System Technical Manual, Part Number: 6-000147. For additional information or assistance, please contact Sotera Wireless or an authorized Sotera Wireless representative in your area.

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1. Preface

1.1 Introduction

This ViSi Mobile Technical Reference Manual is intended to provide information for the care of the ViSi Mobile Monitoring System. This manual is intended to be used by qualified hospital personnel.



Do not operate the ViSi Mobile Monitoring System before reading these instructions.



Bio Meds must complete training by Sotera Wireless, Inc. before utilizing any of these functions.

Intended Use

1.2 Intended Use

The ViSi Mobile Monitoring System is intended for use by clinicians and medically qualified personnel for single or multi-parameter vital signs monitoring of adult patients. It is indicated for ECG (3 or 5 lead wire), respiration rate, heart rate, non-invasive blood pressure (NIBP), non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO₂), pulse rate, and skin temperature in hospital-based facilities; including general medical-surgical floors, intermediate care floors, and emergency departments.

The ViSi Mobile Monitoring System may be used as standalone devices or networked to a ViSi Mobile Remote Viewer through wireless 802.11 communication.

1.2.1 Contraindications

- Impedance pneumography for the determination of Respiration Rate (RESP) is not recommended for use in the presence of mechanically induced high frequency ventilation.
- The ViSi Mobile Monitoring System has not been tested for use on neonatal or pediatric patients under the age of 18 years.
- Do not use the same ViSi Mobile Monitor System to measure the NIBP of one patient while it is connected simultaneously to another patient.
- Do not use the ViSi Mobile Monitor on a patient with an Intra-Aortic Balloon Pump (IABP), or a
 Left Ventricular Assist Device (LVAD). The Monitor requires an unperturbed arterial pulse
 waveform for non-invasive blood pressure calculations. IABP and LVAD perturb the arterial pulse
 waveform.
- Do not use the ViSi Mobile Monitor System on a patient on cardio-pulmonary bypass.
- Do not use the ViSi Mobile Cuff Module on a patient's arm where the use of a blood pressure cuff
 is contraindicated.
- Do not use the ViSi Mobile Monitoring System in an MRI Suite.
- The effectiveness of the ViSi Mobile Monitoring System's blood pressure monitoring has not been established in the presence of any dysrhythmias.



2. ViSi Mobile Warnings and Cautions

2.1 Introduction

Please read and adhere to all warnings, cautions and notes listed here and in the associated sections throughout this manual.

Do not operate the ViSi Mobile Monitoring System before reading these instructions.



Warning statements alert the user to conditions or practices that could result in injury to a person, or serious adverse events associated with the use or misuse of the ViSi Mobile Monitoring System.



Caution statements alert the user to conditions or practices that could result in problems with the ViSi Mobile Monitoring System associated with its use or misuse.

Note: Statements provide supplemental information to the user.

2.2 Warnings /!

Intended Use

Do not use the ViSi Mobile Monitoring System or Power Pack outside the intended use described in this manual. Doing so can result in a delay in or inappropriate therapy.

Do not use the ViSi Mobile Monitoring System in neonatal or pediatric patients (under the age of 18 years) since the System has not been evaluated for these patient groups. Do not use the ViSi Mobile Monitor as a primary hypoxia diagnostic tool.

Safety

The ViSi Power Pack is not intended to be worn by the patient.

Do not modify the ViSi System in any way.

Do not use the ViSi Mobile Monitor, Cuff Module, Chest Sensor or Power Pack in an MRI suite or a hyperbaric chamber.

The ViSi System is protected against damage from electrosurgery. Avoid electrosurgery burns at the ECG monitoring sites by ensuring the electrosurgery-return circuit is connected properly and monitoring electrodes are located as far as possible from the electrosurgery site.

Monitoring may be temporarily interrupted during the use of electrosurgery in the vicinity of/or on a patient being monitored with a ViSi Mobile Monitoring System. Observe the patient closely while electrosurgery is in use.

To ensure patient safety, use only components and accessories recommended or supplied by Sotera Wireless, Inc. Accessories must always be used in accordance with your facility's policies and the manufacturer's recommendations.

Use only the AC adapter recommended for the ViSi Mobile Charger. Use of other AC adapters may result in damage to the unit.

Do not connect more than one ViSi Power Pack to the ViSi Mobile Monitor simultaneously.

The ViSi Mobile Monitoring System has not been tested in the presence of flammable anesthetics or other flammable agents in combination with air, nitrous oxide, or oxygenenriched environments.

Route all ViSi Mobile Monitoring System cabling to avoid the possibility of patient entanglement or strangulation.

Warnings



To ensure patient safety, the conductive parts of the ECG electrodes, including connectors and other patient-applied components, should not contact other conductive parts, or earth ground, at any time.

Never connect the ViSi Mobile Chest Sensor directly to an AC power outlet.

Never connect the ViSi Mobile Cuff Module directly to an AC power outlet. To recharge the battery, disconnect the Cuff Module from the patient, and then place it in the ViSi Mobile Charger.

Never connect the ViSi Mobile Monitor directly to an AC power outlet. To recharge the battery, disconnect the Monitor from the patient, and then place it in the ViSi Mobile Charger.

Never connect the ViSi Power Pack directly to an AC power outlet. To recharge the battery, disconnect the Power Pack from the patient, and then place it in the ViSi Mobile Charger.

Do not touch the electrical contacts on the ViSi Power Pack or use the ViSi Power Pack without it first being inserted into the ViSi Power Pack Cradle. Doing so may result in electric shock from the battery.

When not in use, disconnect the ViSi Power Pack from the Monitor.

Do not modify the ViSi Power Pack in any way.

If the ViSi Power Pack beeper/buzzer sounds or the Red LED is permanently lit, the ViSi Power Pack should be disconnected from the patient immediately.

To prevent possible cross-contamination, properly clean and disinfect all reusable components between patients.

The ViSi Mobile Monitor should never be used to measure the NIBP of one patient while the Monitor is simultaneously connected to another patient.

Do not attempt to take NIBP measurements with the ViSi Mobile Monitor while the patient is undergoing cardio-pulmonary bypass.

Do not attempt to take NIBP measurements with the ViSi Mobile Monitor while the patient is being treated with an intra-aortic balloon pump or left ventricular assist device.

Periodically observe the patient's arm for signs of impaired circulation, which may be a result of NIBP measurements made too frequently. Loosen or remove the ViSi Mobile Disposable Cuff if signs and/or symptoms of prolonged impaired circulation are evident.

Never place the ViSi Mobile Monitor, the ViSi Mobile Cuff Module, or the ViSi Power Pack into the ViSi Mobile Charger while connected to a patient.

Warnings

Do not clean the ViSi Mobile Monitor, Cuff Module, Chest Sensor, Thumb Sensor, or ViSi Power Pack with detergents while worn by the patient.

Do not place the ViSi Mobile Monitoring System or ViSi Power Pack on or over an implanted programmable medical device.

When the "Monitor Too Hot" alarm is in progress, the ViSi Mobile Monitor and Chest Sensor should be removed from the patient immediately. Leaving them on the patient for an extended period of time may lead to a skin burn.

When the "Cuff Battery Temp" alarm is in progress, the ViSi Mobile Cuff Module should be removed from the patient immediately. Leaving it on the patient for an extended period of time may lead to a skin burn.

Disposable Components

All disposable components of the ViSi Mobile Monitoring System are for single patient use only. To avoid possible cross contamination, do not reuse any disposable items on a patient other than the original patient. Dispose of the components and any packaging material after use per your facility's policy or national requirements.



Patient Monitoring

Do not connect more than one ViSi Mobile Monitor to a patient.

Do not connect more than one patient to a single ViSi Mobile Monitor.

The ViSi Mobile Monitor, Thumb Sensor, Cuff Module, and the Chest Sensor must all be connected to the same arm for the System to function correctly.

The Wrist Strap should securely hold the ViSi Mobile Wrist Cradle in place without impairing circulation. Immediately loosen the Wrist Strap if the patient complains of pain, tingling, or numbness in the affected hand or wrist.

Only use the ViSi Mobile Chest Sensor provided by Sotera Wireless, Inc. for the ViSi Mobile Monitoring System. The Chest Sensor is designed to provide defibrillation protection as indicated in the Specifications section of this manual. ViSi Mobile is designed to be compatible with the use of external defibrillators.



Only use the ViSi Mobile Thumb Sensor provided by Sotera Wireless, Inc. with the ViSi Mobile Monitoring System. Using non-approved Thumb Sensors may result in inaccurate SpO₂ readings or damaged equipment.

Warnings

The ViSi Mobile Thumb Sensor is intended for use on the patient's thumb, index and middle finger for SpO₂ measurements; however, cNIBP can only be measured while on

the patient's thumb. Warnings

Inspect the patient's skin at the sensor site per your facility's protocol. If the skin surface has been compromised, reposition the ViSi Mobile Thumb Sensor or move the Thumb Sensor to the patient's other thumb. If the thumb sensor is moved to the other thumb, move the other sensors as well.

Ensure that the ViSi Mobile Thumb Sensor is securely fastened. A Thumb Sensor that is wrapped too tightly or too loosely can adversely affect SpO₂ measurement.

The Thumb Wrap should securely hold the ViSi Mobile Thumb Sensor in place without impairing circulation. Immediately loosen the Thumb Wrap if the patient complains of pain, tingling, or numbness in the affected thumb.

To prevent settings from being inadvertently changed, lock the ViSi Mobile Monitor screen (if enabled) as soon as tasks are completed.

Keep all pacemaker patients under close or constant observation. Pacemaker signals can differ among pacemakers, ICDs, or CRT devices. The Association for the Advancement of Medical Instrumentation (AAMI) cautions: "In some devices, rate meters may continue to count the pacemaker rate during occurrences of cardiac arrest or some arrhythmias. Do not rely entirely upon rate meter alarms".

ViSi cNIBP has not been evaluated in patients with pacemakers that pace the ventricle. ViSi's NIBP may be used instead.

After monitoring has been stopped on the ViSi Mobile Monitor, and the patient has been removed from the Remote Viewer, this action cannot be undone. Once removed, the patient's monitoring session data will no longer be available on the Remote Viewer.

A qualified clinician must always be in direct view of the ViSi Mobile Remote Viewer. If the Remote Viewer display is blank, contact your biomedical engineer immediately for service.

If a ViSi Mobile Monitor or the ViSi Mobile Remote Viewer display screen is scratched or damaged, immediately send it for servicing. A scratched or damaged screen can interfere with patient monitoring.

Always consult Sotera Wireless, Inc. before performing any changes to the ViSi Mobile Appliance. Server changes can result in communication failure between components of the ViSi Mobile Monitoring System. If system communication stops, monitor patients at the ViSi Mobile Monitors.

Case 1:22-cv-01378-MN-JLH Document 175-1 Filed 07/14/23 Page 36 of 561 PageID #: 10615 Warnings

Perform a risk assessment and verification before implementing a change or modification to the IT infrastructure. Changes to IT network configurations can compromise continuous vital signs monitoring and alarm delivery. **Vital Signs**

If a vital signs measurement is questionable, retake the measurement. If the result is still questionable, use a different method of measurement.

ViSi Mobile blood pressure measurements (NIBP and cNIBP) have not been clinically evaluated in the presence of atrial or ventricular arrhythmias. Use alternative BP methods if these arrhythmias are present.

Chest Sensor: ECG, Respiration, Temperature (Skin)

Use all of the same type of high quality ECG electrodes on the patient. Mixing ECG electrode types can adversely affect ECG monitoring.

Avoid placing the ViSi Mobile Cable Securements and ECG electrodes over areas of abrasions, irritation, or other sensitive areas. If possible, remove, reposition, and replace ECG electrodes and Cable Securements if the patient complains of pain/itching at the sites.

The ViSi Mobile Monitor does not provide automated arrhythmia analysis. As a result, certain arrhythmias may cause the Monitor to display variable heart rates. If frequent arrhythmias are suspected, their presence should be confirmed by visual observation of the ECG waveform or another method, such as a 12-lead ECG.

The ViSi Mobile Monitor does not provide ST segment analysis. Therefore, if a change in the ST segment of the ECG waveform is suspected, it should be confirmed by another method, such as a 12-lead ECG.

Pacemaker signals can differ among pacemakers, ICDs, or CRT devices. The Association for the Advancement of Medical Instrumentation (AAMI) cautions: "In some devices, rate meters may continue to count the pacemaker rate during occurrences of cardiac arrest or some arrhythmias. Do not rely entirely upon rate meter alarms". All pacemaker patients should be kept under close or constant observation.

External pacemakers or other external electrical stimulators may cause the ViSi Mobile Monitor to produce erroneous results.

RESP (chest wall motion) can continue in the absence of ventilation (obstructed airway). Do not rely on the RESP alone to determine adequacy of ventilation. Other vital signs, such as HR and SpO₂, should be assessed as well.

TEMP monitoring with the ViSi Mobile Monitoring System is intended for trending purposes only and is not intended to replace core temperature monitoring. Before making clinical decisions based on the skin temperature measurement, verify the measurement using another clinically acceptable method of core temperature measurement.

Warnings 1

Impedance pneumography for the determination of respiration (RESP) is not recommended for use in the presence of mechanically induced, high frequency ventilation.

Cuff Module / NIBP

ViSi Mobile Disposable Cuffs are for single patient use only. To avoid possible cross contamination, do not reuse a Cuff on a patient other than the original patient.

The ViSi Mobile Disposable Cuff should be snug enough to support the Cuff Module while not impairing circulation when deflated.

Avoid applying the ViSi Mobile Disposable Cuff over a wound as this can cause further injury.

Avoid applying the ViSi Mobile Disposable Cuff on any limb where intravascular access or therapy, or an arterio-venous (A-V) shunt, is present because of temporary interference to blood flow which could result in injury to the patient.

Take care in the application of the ViSi Mobile Disposable Cuff when applying the Cuff to an arm on the same side of a mastectomy. Recommend using the ViSi Mobile Monitoring System on the opposite arm.

ViSi Mobile NIBP measurements (1-time measurements or continuous measurements) have not been clinically evaluated in the presence of atrial or ventricular arrhythmias. Use alternative BP methods if these arrhythmias are present.

Inflate the ViSi Mobile Disposable Cuff only after proper application to the patient's limb.

If you are uncertain of the reliability of an NIBP measurement, repeat the measurement. If the reading is still suspect, use another method to measure the blood pressure.

SpO₂

Oxygen saturation measurements using SpO₂ are dependent on proper sensor placement, exposure to ambient light conditions, and general patient conditions. Before making clinical decisions based on SpO₂ measurements, verify the measurement using another clinically acceptable method, such as arterial blood gas analysis.

High ambient light conditions, including direct sunlight, may interfere with the performance of the ViSi Mobile Thumb Sensor.



Low perfusion, electrosurgical devices, dysfunctional hemogolobin, the presence of certain dyes and inappropriate positioning of the ViSi Mobile Thumb Sensor may result in erroneous measurements.

Alarms / Alerts

When alarms are paused, there is no notification of a potentially clinically significant change in the patient's vital signs. Observe the patient by other means when alarms are paused.

When alarms are turned OFF, there is no notification of a potentially clinically significant change in the patient's vital signs. Observe the patient by other means when alarm limits are set to OFF.

Once Auto Set is selected (on the ViSi Mobile Monitor), review the newly calculated alarm limits carefully before deciding to confirm or cancel the new alarm limits. Once new alarm limits are confirmed on the ViSi Mobile Monitor, they cannot be changed back to the original pre-set limits from the ViSi Mobile Monitor. Use the ViSi Mobile Remote Viewing Device to change the alarm limits back to the original pre-set limits.

When the ViSi Mobile Monitor is not connected or loses wireless connection to the ViSi Mobile Appliance, the ViSi Mobile Remote Viewer does not receive patient alarms or alerts from the ViSi Mobile Monitor.

When the last source of monitoring is lost due to equipment (such as thumb sensor off, ECG leads off, all sensors disconnected) the visual annunciation of the alert will not have an audible component.

Line isolation monitor transients (artifacts) may resemble actual cardiac waveforms and inhibit heart rate alarms. Ensure correct electrode placement and cable arrangement to minimize line isolation monitor transients.

To avoid possible hearing damage, do not place your ear too close to the ViSi Mobile Monitor when it is alarming audibly.

When the ViSi Mobile Monitor alarms or alerts, check the patient first to confirm that there is no immediate danger to the patient.

When testing the speaker at the ViSi Mobile Remote Viewer, you are testing how the alarm and alert tones will sound at the Remote Viewer during typical operation. If the volume is inadequate, clinicians could miss alarms and alerts. During testing, if the tone does not sound or it is not loud enough, adjust the speaker volume. If the sound is still not loud enough, immediately contact a biomedical engineer.

The ViSi Power Pack Alarms/Alerts DO NOT audibly annunciate on the ViSi Mobile Monitor or the Remove Viewing Device.



If the ViSi Mobile Monitor displays a "Battery Pack Fault", "Electric Shock", or "Monitor Too Hot" message, disconnect the Power Pack immediately.

Warnings

User Maintenance

To avoid contaminating or infecting personnel, the environment or other equipment, make sure to disinfect and decontaminate the ViSi Mobile Monitoring System, Thumb Sensor and disposables appropriately before disposing of them in accordance with your country's laws for equipment containing electrical and electronic parts. *Wireless Communications*

When the ViSi Mobile Monitor is not configured to connect to the facility's network or loses wireless connection to the ViSi Mobile Appliance, the ViSi Mobile Remote Viewer does not receive patient alarms or alerts from the ViSi Mobile Monitor.

All wireless devices are susceptible to radio frequency interference that can disrupt connectivity. If excessive ViSi Mobile Monitoring System disconnections are observed, notify your biomedical engineer. Excessive disconnections can cause interrupted patient monitoring; disconnections must be investigated and corrected.

Other RF radiating devices (such as high powered RFID readers and Bluetooth devices) that are in close proximity with the ViSi Mobile Monitor may interfere with the Monitor's wireless communications. During such interference, the Monitor continues to monitor and will alarm locally. If wireless communication is affected when using the Monitor in close proximity with another RF radiating device, move the other device away from the Monitor or discontinue use of the other device. If you have any concerns regarding a cyber security breach or vulnerability, contact Sotera Wireless, Inc. or an authorized Sotera Wireless, Inc. representative in your area.

Off-The-Shelf (OTS) Software

The use of any software other than those specified in this manual will violate the safety, effectiveness and design controls of this medical device and such use may result in an increased risk to users and patients.

2.3 Cautions

Intended Use

Federal (U.S.A.) law restricts the ViSi Mobile Monitoring System and Power Pack to the sale, distribution, or use by, or on the order of a licensed medical practitioner.

The effectiveness of the ViSi Mobile Monitoring System's blood pressure monitoring has not been established in pregnant, including pre-eclamptic, patients.

General

Placing the ViSi Mobile Monitor into the Charger when the "All Sensors Disconnected" alert is displayed will result in the patient's monitoring session being stopped. It is recommended that you follow the correct stop/pause monitoring flows.

When monitoring has been paused, monitoring may only be resumed using the same ViSi Mobile Monitor. If you place the ViSi Mobile Monitor into the Charger with other Monitors, label the Monitor so that is can be identified when monitoring is to be resumed.

Moving the ViSi Mobile Monitor out of the network range will break the radio link, immediately stopping communication of patient vital signs data to the ViSi Mobile Remote Viewer.

When the wireless connector symbol is yellow, the ViSi Mobile Monitor is unable to connect to the ViSi Mobile Remote Viewer (via the ViSi Mobile Appliance).

Only the ViSi Power Pack should be placed into the accompanying cradle.

To avoid damage, the ViSi Power Pack should only be connected to the ViSi Mobile® Monitor.

Monitoring

The accuracy of cNIBP is dependent on the initial cuff calibration. Use good clinical practice to confirm cNIBP accuracy before initiating or treating a patient.

The accuracy of the cNIBP measurement cannot be relied upon in patients with a BMI greater than 35.

Due to cNIBP signal averaging, there is a time delay of up to 120 seconds between the instantaneous blood pressure reading and the displayed reading.

The ViSi Mobile Monitoring System accuracy claim (mean error of $\leq \pm 5$ mmHg and a std. dev. of ≤ 8 mmHg) is not met when the subject is in a semi-Fowlers position (inclined more than 30 degrees from horizontal).

Cautions

2-way radios may cause waveform distortion when placed within 1 foot of the ViSi Mobile Monitor.

Some brands of television may cause temporary waveform distortion and data loss when placed within 6 feet of the ViSi Mobile Monitor.

Safety

The ViSi Mobile Monitoring System or Power Pack have not been tested in the presence of flammable anesthetics or other flammable agents in combination with air, nitrous oxide, or oxygen-enriched environments.

Do not use a ViSi Mobile Monitor, its components, Power Pack or other accessories that appear damaged. Inspect all reusable components for damage before each use.

Do not attempt to connect any patient worn component, ViSi Chest Sensor or ViSi Mobile Cuff Module, or ViSi Power Pack to an electrical outlet of any kind.

A component that has been dropped or severely abused should be checked by qualified service personnel before use on a patient.

The ViSi Mobile Monitoring System or Power Pack are not intended for home use.

Do not use the ViSi Mobile Monitoring System or Power Pack to monitor a patient in a wet environment, such as a shower.

Explosion Hazard. Do not use in the presence of a flammable anesthetic mixture with air, or with oxygen or nitrous oxide.

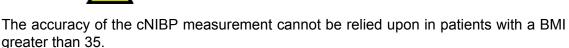
Use care when using automatic cuff inflation for prolonged periods on unconscious or semi-conscious patients since the patient may not be able to alert the clinician to any pain he/she may be experiencing. Pressing the "Stop NIBP" button interrupts the NIBP measurement and deflates the cuff.

Consult your Biomed department or vendors for assistance in identifying EMC compliance status of other medical devices when using the ViSi Mobile Monitoring System or Power Pack.

Using accessories other than those specified may result in increased electromagnetic emission or decreased electromagnetic immunity of the monitoring equipment.

Changes in posture and arm height can affect ViSi cNIBP accuracy. If the cNIBP measurement is questionable, retake the measurement. Ideally recalibrate in the same position as the initial calibration.

Cautions /



Due to cNIBP signal averaging, there is a time delay between the instantaneous blood pressure reading and the displayed reading.

You should manually recalibrate cNIBP after the administration of an IV vasoactive drug or a new oral vasoactive drug. The Calibrate cNIBP alert will not be displayed.

If using the ViSi Mobile Monitor with any other monitor on the same patient, check that each monitor does not interfere with the operation of the other. If interference is detected, remove one or more of the sensors until there is no longer any interference.

Service / Maintenance

If the ViSi Mobile Monitor detects an unrecoverable problem, an error message containing the error number is displayed. Remove the Monitor from use and report the error to Sotera Wireless, Inc Customer Service.

When the ViSi Mobile Monitor is in the Charger and a charging alert occurs, remove the Monitor from service.

General maintenance of the ViSi Mobile Monitoring System should be conducted at the hospital defined intervals.

The ViSi Mobile Monitoring System components, including the ViSi Power Pack should only be serviced by Sotera Wireless, Inc. technicians or authorized service providers.

Equipment / Components

If the ViSi Mobile Monitor is to be stored for an extended period of time, it is recommended the Monitor be stored with the Shipping Plug inserted to reduce the battery discharge. The ViSi Mobile Monitor must always have the Shipping Plug inserted when shipped by a common carrier to comply with Federal Regulations regarding electromagnetic emissions.

When inserting the ViSi Mobile Monitor into the Wrist Cradle, ensure proper alignment: flat end to flat end, with the round end pointing towards the wrist.

Selection of the correct ViSi Mobile Disposable Cuff size is necessary to ensure accurate NIBP measurements. A Cuff that is too small can result in a falsely high NIBP measurement. A Cuff that is too large can result in a falsely low NIBP measurement.

Avoid touching the ViSi Mobile Disposable Cuff during cuff inflation as it may disrupt the

measurement. Cautions



To avoid damage from dropping the ViSi Mobile Monitor, ensure that the Wrist Strap is snugly wrapped around the wrist.

To avoid damage from dropping the ViSi Mobile Monitor while it is connected to the patient, secure the ViSi Mobile Monitor by plugging in the thumb sensor or locking key.

The performance of the automated sphygmomanometer may be affected by extremes of temperature, humidity and altitude.

Cautions

The ViSi Mobile Monitoring System may not perform to specification if stored or shipped outside the specified temperature range.

The ViSi Mobile Monitor may be temporarily interrupted by UHF RFID Systems (860-960MHz).

When using a ViSi Power Pack equipped with a mount, ensure the clamp is properly secured to the bedside or IV Pole to avoid damage from being dropped.

Avoid from putting the ViSi Power Pack directly below an IV bag.

Avoid putting anything other than the ViSi Power Pack into the cradle.

Route the ViSi Power Pack cable away from other medical equipment in its vicinity.

Cleaning / Disinfecting

Do not clean the ViSi Mobile Monitor, the Cuff Module, or the Power Pack while it is plugged into the ViSi Mobile Charger.

Do not apply liquid to the ViSi Mobile Cuff Module or the Power Pack. To clean, use a damp cloth.

Ensure the sensor connector contacts are thoroughly dried to prevent possible malfunction.

Thumb sensors which are saturated with liquid should be allowed to air dry thoroughly before re-use.

Do not use bleach, abrasive cleaning agents or organic solvents on any of the ViSi Mobile Monitoring System components.

Use only recommended cleaning/disinfecting agents to prevent damage to the device and components. See page 107

Do not autoclave the ViSi Mobile Monitor, its components, or accessories.

Do not use excessive amounts of liquid when cleaning the ViSi Mobile Chest Sensor or the ViSi Mobile Thumb Sensor.

Cautions



After patient use, the disposables from the ViSi Disposable Kit may contain bio-hazard materials. Handle and dispose of these items according to your facility's policies.

When the ViSi Mobile Cuff Module is connected to the other ViSi Mobile Components, the entire system has an ingress protection rating of IPX0.

Notes

2.4 Notes

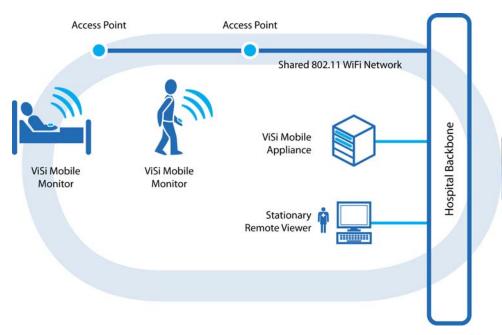
Note: Figures in this manual are provided for reference purposes only. Screens may differ based on the monitoring device configuration, licenses available, parameters selected and patient configuration of the ViSi Mobile Monitoring System.

Note: All ViSi Mobile Monitoring System alarms and alerts annunciate with icons and colors that comply with IEC 60601-1-8.



3. Theory of Operation

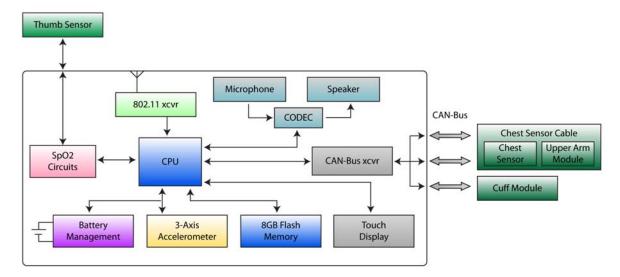
3.1 Introduction



ViSi Mobile Monitoring System

The ViSi Mobile Monitoring System enables clinicians to remotely monitor patients who are connected to ViSi Mobile Monitors. The System includes ViSi Mobile Monitors, a ViSi Mobile Appliance and a ViSi Mobile Remote Viewer. Information flows wirelessly and bi-directional between components.

Introduction



ViSi Mobile Patient-Worn Monitor

The ViSi Mobile Patient-Worn Monitor continuously measures ECG/Heart Rate, Respiration Rate, NIBP, Skin Temperature, and SpO₂. The ViSi Mobile Monitor uses IEEE standards-based wireless communications to talk to the ViSi Mobile Appliance.

The main sub-components of the ViSi Mobile Patient-Worn Monitor are the ViSi Mobile Monitor, Chest Sensor Cable, Cuff Module and Thumb Sensor. These sub-components are connected to each other by a digital bus. The system is designed to strengthen the afferent limb of rapid response systems.

Each sub-component has specialized components for directly converting analog physiologic signals to the digital domain. Digitization of biological signals close to the sensors eliminates analog signal traversing cables found in traditional monitors that can cause artifact nuisance alarms. The on-body consolidation of all routine vital signs also reduces or eliminates the "spaghetti factor" found in current multi-parameter beside monitors that impede patient comfort and mobility.

The Chest Sensor, Upper Arm Module and Mobile Monitor each contain a three-axis accelerometer.

3.2 ViSi Mobile Monitor

The ViSi Mobile Monitor serves as the hub of the patient-worn digital network. In this case, the Mobile Monitor supports the capture, storage, display, and alarming of all components. Measured vital signs with access to waveforms can also be displayed on a screen for clinician viewing.

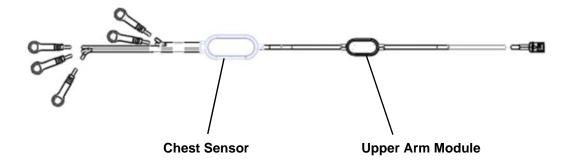


Within the ViSi Mobile Monitor, a connector at the distal end facing the hand provides connection to a ViSi Mobile Thumb Sensor for pulse oximetry measurements or ViSi Mobile Mode Plugs for biomedical service and shipping. Three digital bus connectors on the opposite end provide digital connection to the ViSi Mobile Chest Sensor Cable (measuring ECG and posture), ViSi Mobile Cuff Module (measuring non-invasive blood pressure, NIBP), and future parameters. A speaker is incorporated to provide alarm annunciation.

The ViSi Mobile Monitor also provides wireless connectivity. The Wi-Fi 802.11b/g/n Monitor supports bidirectional communications to a dedicated ViSi Mobile Appliance located in the IT datacenter. TCP/IP protocols are used for all data, and the maximum data rate generated by the device when all parameters and waveforms are active is less than 20 KBps. In all such devices, security is an important design consideration. In this case, data security is ensured with Wi-Fi Protected Access 2 – Pre-Shared Key (WPA2-PSK) encryption.

The ViSi Mobile Monitor allows for submersion for cleaning and disinfection between patient uses.

3.3 ViSi Mobile Chest Sensor Cable



The Chest Sensor Cable (for either three- or five-lead ECG monitoring) is attached to the patient's upper torso near the midline. The back of the Chest Sensor incorporates a skin surface temperature sensor. Although skin surface temperature will differ from core body temperature, upward trends may indicate a rising fever.

Independent ECG channels are sampled at 500 Hz and include pacemaker detection, lead(s) off, and impedance respiration. A microprocessor detects beats and calculates heart rate (HR). Resulting waveforms, HR values and status (such as leads-off) are communicated to the ViSi Mobile Monitor via the digital bus.

ViSi Mobile Cuff Module (NIBP)

The Upper Arm Module is used to correct for hydrostatic pressure used in the determination of continuous non-invasive blood pressure. It also serves as a mechanical anchor to the cable from the ViSi Mobile Monitor to the Chest Sensor Module.

The accelerometers within the Chest Sensor and the Upper Arm Module provide three axis posture, changes in posture and measures of motion. Motion is used to suspend respiration calculations in presence of motion artifact to reduce false alarms.

3.4 ViSi Mobile Cuff Module (NIBP)

The NIBP function is contained within the ViSi Mobile Cuff Module that connects directly to a ViSi Mobile Disposable Cuff (supplied by Sotera Wireless). The module includes an integrated battery, dual microprocessors, and a digital bus connector.

Blood pressure measurements are determined during the cuff inflation cycle rather than the deflation cycle. Measurements taken during inflation avoids over-inflation and lowers overall power consumption and measurement time.



Measurements are passed to the ViSi Mobile Monitor for display; there is no display on the ViSi Mobile Cuff Module.

3.5 ViSi Mobile Thumb Sensor

The Thumb Wrap holds the Thumb Sensor and secures it to the base of the patient's thumb. The Thumb Sensor is connected to the ViSi Mobile Monitor at the rounded end of the Monitor.



3.6 ViSi Mobile Remote Viewer / Appliance

Data originating from the ViSi Mobile Patient-Worn Monitor are similar to requirements for voice over Internet Protocol (VOIP) telephony applications. In the ViSi Mobile Monitoring System, data is captured in the ViSi Mobile Appliance which acts as an enterprise hub. The Appliance is dedicated hardware installed in the IT datacenter for secure network connectivity and emergency power backup.

A secure remote access (similar to a VPN) connection allows remote service support and software updates.

Clinical data from up to 32 patients can be displayed on a single ViSi Mobile Remote Viewer. Patients are manually admitted to the ViSi Mobile Monitoring System.

3.7 Alarm Management

Alarms originate from the ViSi Mobile Monitor. A bidirectional interface (via the ViSi Mobile Appliance) ensures remote alarm annunciation on the ViSi Remote Viewer(s). Remote Viewer(s) display both waveforms and alarm values as well provide an interface for a clinician to silence an alarm. Visual icons and audible annunciation conform to the IEC 60601-1-8 standard.

Threshold alarms are set at factory default values but may be reconfigured at installation. Audio alarm annunciation can be delayed based on alarm type, severity, and preconfigured time. Audio alarm delays allow filtering of short duration nuisance alarms.

Alarm annunciation delays have been shown to reduce nuisance alarms by adding a simple rule of persistence to the vital signs value. When a non-life threatening alarm is annunciated, the audio component of the annunciation is deferred to the ViSi Remoter Viewer(s) for a short period of time. This reduces the disturbances to the patient.

Activating autoset (from the ViSi Mobile Monitor) changes all alarm parameters that are currently in alarm to new set points depending on the patient's current condition. The degree of change depends on the current patient value compared to default alarm limits. Patient alarm settings may also be changed from the ViSi Remote Viewer, which is in line with other types of multi-parameter monitoring systems.

3.8 ViSi Mobile Charger

The ViSi Mobile Charger is used to charge both ViSi Mobile Monitors and Cuff Modules, providing two or eight charging docks for simultaneously charging multiple units. The Charger consists of a desktop/wall mount charger, power supply and power cable.

The LED on the Charger is used to indicate the charging status of devices that are currently inserted:

LED Color	Charging Status	
Steady Green	Everything is functional:No devices in the Charger.All devices are charging normally or are fully charged.	
Flashing Green / Yellow	At least one device in the Charger has not properly registered with the Charger, but charging continues on all devices. Devices with fully drained batteries cannot register with the Charger until after a charge cycle starts and will cause this condition until they reach a minimum charge level. Removing and reinserting an unregistered device can give it another chance to register in the Charger. If this condition is repeatedly observed on devices that are not fully drained, contact Sotera Wireless or an authorized Sotera Wireless representative in your area.	
Steady Yellow	At least one device in the Charger is not being charged due to a fault with the device. All other devices are charging. Contact Sotera Wireless or an authorized Sotera Wireless representative in your area.	
Steady Red	Charger fault. No devices are charging, the Charger has shutdown. Contact Sotera Wireless or an authorized Sotera Wireless representative in your area.	

Case 1:22-cv-01378-MN-JLH Document 175-1 Filed 07/14/23 Page 52 of 561 PageID #: 10631 ViSi Mobile Charger

- Notes -



4. Specifications

4.1 Introduction

This section provides specifications regarding measurement ranges, accuracy levels and environmental operating conditions for the ViSi Mobile Monitoring System.



Do not use the ViSi Mobile Monitoring System in neonatal or pediatric patients (under the age of 18 years) since the System has not been evaluated for these patient groups. Do not use the ViSi Mobile Monitor as a primary hypoxia diagnostic tool.

4.2 Vital Sign Measurements

4.2.1 Heart Rate

Heart Rate				
Display Range	0 to 240 BPM			
Accuracy Range	30 to 240 BPM	30 to 240 BPM		
Accuracy	±3 BPM			
Resolution	1 BPM			
Pacemaker	 The monitor detects and rejects pacemaker impulses in accordance with ANSI/AAMI/IEC 60601-2-27:2011 - Performs heart rate calculations on a patient with a pacemaker Will not recognize a pacemaker impulse as a QRS Displays pacer markers on ECG waveforms 			
Pacemaker Pulse Rejection Without Overshoot	Pulse Rejection Range: Indicated Heart Rate:	2 60601-2-27:2011 , 201.12.1.101.13: Amplitude from ±2 mV to ±700 mV Pulse Width from 0.1 ms to 2 ms		
	Ventricular Pacing:	Case (a): 0 BPM Case (b): 60 BPM Case (c): 30 BPM		
	Atrial / Ventricular Pacing:	Case (a): 0 BPM Case (b): 60 BPM Case (c): 30 BPM		
		Note: At 30 BPM, asynchronous pacing may trigger occassional R-wave detection		

Heart Rate				
Pacemaker Pulse Rejection	Tested per ANSI/AAMI/IEC 60601-2-27:2011 , 201.12.1.101.13, Method A:			
With Overshoot	Pulse Rejection Range:	Amplitude from ± 2 mV to ± 700 mV Pulse Width from 0.1 ms to 2 ms		
		Note: Pulses with polarization overshoot > 4 ms may cause R- wave		
	Indicated Heart Rate:			
	Ventricular Pacing:	Case (a): 0 BPM Case (b): 60 BPM Case (c): 30 BPM		
	Atrial / Ventricular Pacing:	Case (a): 0 BPM Case (b): 60 BPM Case (c): 30 BPM		
		Note: At 30 BPM, asynchronous pacing may trigger occassional R-wave detection		
Defibrillation Response	 Defibrillator protected Displays HR measurement < 30 seconds after a defibrillation event Displays an ECG waveform < 10 seconds after a defibrillation event 			
	Note: Defibrillation events may be implanted or external.			
		overy is dependent upon using proper des. Use only Ag-AgCl disposable		
T-Wave Rejection	• T-waves up to 1.65 mV	50601-2-27:2011, 201.12.1.101.17: 7 in amplitude: no change in indicated heart rate.		
Heart Rate Averaging	Tested per ANSI/AAMI/IEC 60601-2-27:2011, 201.7.9.2.9.101, b) 3): • 20 second moving average			
Heart Rate Accuracy and Response to Irregular Rhythm	Tested per ANSI/AAMI/IEC 60601-2-27:2011, 201.7.9.2.9.101, b) 4): • Waveform 3a: 80 BPM • Waveform 3b: 60 BPM • Waveform 3c: 60 BPM • Waveform 3d: 90 BPM			
Change in Heart Rate	Tested per ANSI/AAMI/IEC • 80 BPM to 120 BPM: • 80 BPM to 40 BPM:			
Time to Alarm for Cardiac Standstill	Tested per ANSI/AAMI/IEC • < 15 seconds	60601-2-27:2011 , 208.6.6.2.103:		
Time to Alarm for Low Heart Rate	Tested per ANSI/AAMI/IEC • < 15 seconds	60601-2-27:2011 , 208.6.6.2.103:		

Vital Sign Measurements

Heart Rate	
Time to Alarm for High Heart Rate	Tested per ANSI/AAMI/IEC 60601-2-27:2011 , 208.6.6.2.103: < 15 seconds
Time to Alarm for Tachycardia	Tested per ANSI/AAMI/IEC 60601-2-27:2011, 201.7.9.2.9.101, b) 6): Figure 4a: • 12 seconds • Gain = 2.0x: <12 seconds • Gain = 0.5x: < 5 seconds Figure 4b: • Gain = 1.0x: < 10 seconds • Gain = 2.0x: <10 seconds • Gain = 0.5x: < 5.5seconds
Input Impedance	> 20 Mohms
Frequency Response	0.5 to 125Hz
Lead Off Detection Current	< 24 nA
Common Mode Rejection Ratio	> 85 dB

Vital Sign Measurements

4.2.2 Respiration

Respiration		
Method	Impedance Pneumography	
Display Range	0 to 50 BR/MIN	
Accuracy Range	3 to 50 BR/MIN	
Accuracy	± 3 BR/MIN or 10% of reading, whichever is greater	
Resolution	1 BR/MIN	
Respiration Drive	Voltage: 1.00 V P-P ±5%	
	Frequency: 32.0 KHz ±2%	

4.2.3 Pulse Oximetry (SpO₂, Functional Oxygen Saturation)

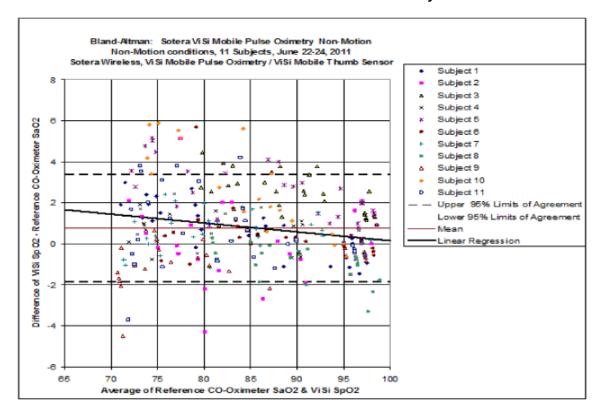
Normative Reference	ISO 9919: 2005	
SpO_2	Display Range	49 to 100%
	Accuracy Range	70 to 100%
	Accuracy	≤ 2% from 70-100% (no motion) ^a Unspecified from 49-69%
	Resolution	1%
Pulse Rate	Display Range	0 to 240 BPM
	Accuracy Range	30 to 240 BPM
	Accuracy (No Motion)	± 3 BPM; < 50 BPM @ ≥ 0.6% Pulsatile Modulation ± 3 BPM; ≥ 50 BPM @ ≥ 0.4% Pulsatile Modulation
	Accuracy (RMS Error)	≤ 3 BPM
	Rate Resolution	1 BPM
Validation Study	and validated against huma	O_2 is calibrated to display functional oxygen saturation n subjects arterial blood sample reference measured with ltman: ViSi Mobile Pulse Oximetry table).
	Note: A functional tester cannot be used to assess the accuracy of a pulse oximeter probe or a pulse oximeter monitor.	
Calculation Rate	Every pulse	
Display Refresh Rate	Every 3 seconds	
Averaging	12 beat average following initialization	
Alarm Range	Low - Fixed at 85%	
Alarm Delay	30 seconds (fixed)	
Waveform Display	 Amplitude is normalized Sweep speed is scaled to 25mm/sec to match ECG 	
Sensor Application Time	Sensor should be checked every 8 hours	
Optical Wavelengths / power	Red: 660nm / max 6.5mW (±15%) Infra-Red: 905nm / max 5.2mW (±15%)	
Interference	SpO_2 can be adversely affected by the presence of dyshemoglobin, ambient light (including photodynamic therapy); electromagnetic interference; electrosurgical units; dysfunctional hemoglobin; presence of certain dyes; inappropriate positioning of the pulse oximeter sensor.	
Toxicity	Thumb sensor uses white silicone which has no known toxicity effects.	
Measuring Maximum Temperature	Measuring the maximum temperature of the Thumb Sensor at the skin should be done with a calibrated temperature probe placed under the sensor when attached to the thumb.	

a. Bench testing indicates accuracy may be compromised at pulse rates below 50BPM at modulations less than 0.6% and extremely low pulse rates of 30BPM at modulations less than 0.8%.

The table below shows A_{rms} values measured using the ViSi Mobile Thumb Sensor (Model 92-10020) with the ViSi Mobile Monitoring System in a clinical study:

Validation Data (per ISO 9919)				
Age of Volunteers 18 - 45				
SpO ₂ Accuracy (No Motion)				
SpO2 Range 70-100% 90-100% 80-90% 70-80%				
Accuracy (A _{rms}) - No Motion	1.9	1.2	1.9	2.4

Bland-Altman: ViSi Mobile Pulse Oximetry

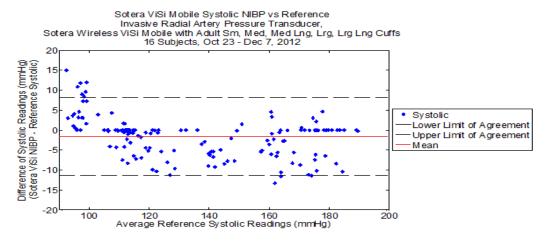


Note: Test subjects were healthy, in an age range from 21 to 45 years (7 males and 4 females), with a wide range of skin pigmentation.

4.2.4 Non-Invasive Blood Pressure (NIBP)

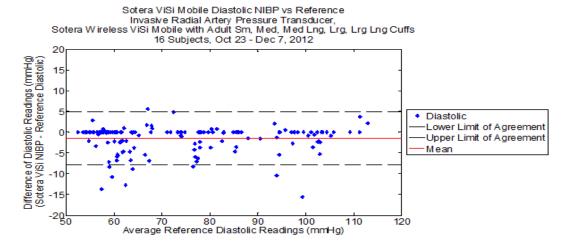
Non-Invasive Blood Pressure (NIBP)			
Normative Reference	ISO 81060-2: Non-invasive Sphygmomanometers - Part 2: Clinical validation of automated measurement type.		
Principle of Operation	Oscillometry		
Systolic	Range:	60 to 240 mmHg	
	Accuracy:	Mean error of less than \pm 5 mmHg and a std. dev. of \leq 8 mmHg	
	Resolution:	1 mmHg	
Diastolic	Range:	40 to 160 mmHg	
	Accuracy:	Mean error of less than \pm 5 mmHg and a std. dev. of \leq 8 mmHg	
	Resolution:	1 mmHg	
Mean Arterial Pressure	Range:	50 to 185 mmHg	
	Accuracy:	Mean error of less than ±5 mmHg and a std. dev. of ≤ 8 mmHg	
	Resolution:	1 mmHg	
Pulse Rate	Accuracy (NIBP) <3 BPM		
Validation Study	Invasive blood pressure (radial artery) reference		
	Number of subjects: 16		
	Subject Age Range: 19-48		

Systolic Bland Altman Analysis (NIBP)



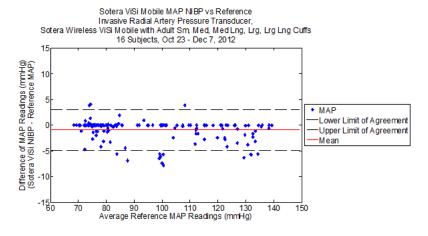
Sample Size:	152 data points
Mean:	-1.65 mmHg
Standard Deviation:	5.01 mmHg
Upper 95% Limits of Agreement (+1.96 SD):	8.2 mmHg
Lower 95% Limits of Agreement (-1.96 SD):	-11.5 mmHg

Diastolic Bland Altman Analysis (NIBP)



Sample Size:	152 data points
Mean:	-1.49 mmHg
Standard Deviation:	3.22 mmHg
Upper 95% Limits of Agreement (+1.96 SD):	4.8 mmHg
Lower 95% Limits of Agreement (-1.96 SD):	-7.8 mmHg

Mean Arterial Pressure Bland Altman Analysis (NIBP)



Sample Size:	152 data points
Mean:	-0.91 mmHg
Standard Deviation:	2.04 mmHg
Upper 95% Limits of Agreement (+1.96 SD):	3.1 mmHg
Lower 95% Limits of Agreement (-1.96 SD):	-4.9 mmHg

4.2.5 Continuous Non-Invasive Blood Pressure (cNIBP)

Continuous Non-Invasive Blood Pressure (cNIBP)			
Normative Reference	ISO 81060-2: Non-invasive Sphygmomanometers - Part 2: Clinical validation of automated measurement type.		
Principle of Operation	cNIBP is based on the relationship between blood pressure and the time it takes a pulse that originates from a cardiac contraction to arrive at a peripheral location.		
Display Update		od pressure is displayed based on averaging PAT calculations from the onds and updating the display every 3 seconds.	
Systolic	Range:	60 to 240 mmHg	
	Accuracy ^{a,b} :	Mean error of $\leq \pm 5$ mmHg and a std.dev. of ≤ 8 mmHg	
	Resolution:	1 mmHg	
Diastolic	Range:	40 to 160 mmHg	
	Accuracy ^{a,b} :	Mean error of $\leq \pm 5$ mmHg and a std.dev. of ≤ 8 mmHg	
	Resolution:	1 mmHg	
Mean Arterial Pressure	Range:	50 to 185 mmHg	
(MAP)	Accuracy ^{a,b} :	Mean error of $\leq \pm 5$ mmHg and a std.dev. of ≤ 8 mmHg	
	Resolution:	1 mmHg	
Validation Study	Invasive blood pressure (radial artery) reference		
	Number of subj	ects: 15	
	Subject age range: 19-48 years		
	Arm circumference range tested: 21-38 cm		

a. ViSi Mobile Monitoring System accuracy claim is not met when the subject is inclined more than 30 degrees from horizontal.

cNIBP Clinical Study Results
Sotera ViSi cNIBP vs. Reference Invasive Radial Artery Transducer (n=15 subjects)

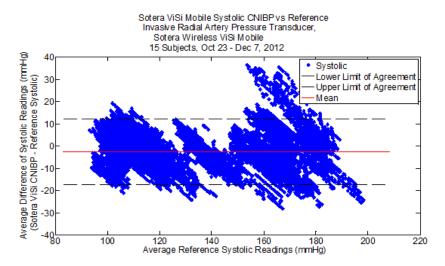
Subject Position		Supine	30°	60°	Overall
Systolic	Bias	-1.61	-4.77	-7.36	-1.88
	Std. Dev.	5.69	7.87	9.97	6.17
Diastolic	Bias	-1.33	-3.97	-8.31	-1.65
	Std. Dev.	3.16	4.49	6.07	3.62
MAP	Bias	-0.33	-3.01	-7.23	-0.67
	Std. Dev.	3.36	5.37	6.67	3.86
Data Points	•	47,572	1,774	1,724	54,179

b. The accuracy and precision of the cNIBP measurement met ISO 81060-2 requirements for the first 2.5 hours of testing.



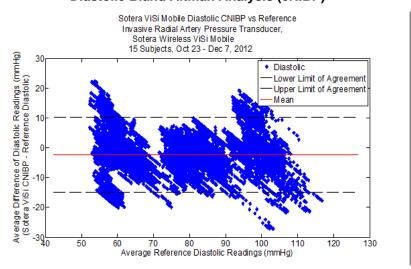
Changes in posture and arm height can affect ViSi cNIBP accuracy. If the cNIBP measurement is questionable, retake the measurement. Ideally recalibrate in the same position as the initial calibration.

Systolic Bland Altman Analysis (cNIBP)



Sample Size:	54,179 data points
Mean:	-1.88 mmHg
Standard Deviation:	6.17 mmHg
Upper 95% Limits of Agreement (+1.96 SD):	10.2 mmHg
Upper 95% Limits of Agreement (-1.96 SD):	-14.0 mmHg

Diastolic Bland Altman Analysis (cNIBP)

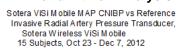


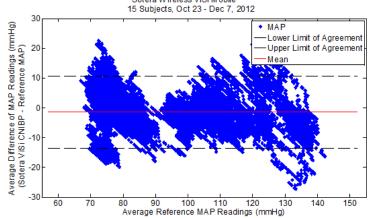
Sample Size:	54,179 data points
Mean:	-1.65 mmHg

Vital Sign Measurements

Standard Deviation:	3.62 mmHg
Upper 95% Limits of Agreement (+1.96 SD):	5.4 mmHg
Upper 95% Limits of Agreement (-1.96 SD):	-8.7 mmHg

MAP Bland Altman Analysis





Sample Size:	54,179 data points
Mean:	-0.67 mmHg
Standard Deviation:	3.86 mmHg
Upper 95% Limits of Agreement (+1.96 SD):	6.9 mmHg
Upper 95% Limits of Agreement (-1.96 SD):	-8.2 mmHg

Vital Sign Measurements

4.2.6 Skin Temperature

Temperature				
Scale	°C		°F	
Range / Accuracy	Range	Accuracy	Range	Accuracy
(measurement at approximately 102 kPa	0° - 19.9°	±0.3°	32° - 67.9°	±0.5°
/ 768 mmHg)	20° - 24.9°	±0.3°	68° - 76.9°	±0.5°
	25° - 35.9°	±0.2°	77° - 96.7°	±0.3°
	36° - 39.9°	±0.1°	96.8° - 103.9°	±0.2°
	40° - 41.9°	±0.2°	104° - 107.5°	±0.3°
Resolution	± 0.1°		± 0	.1°
Transient Response	< 6 min (25° - 37°)		< 6 min (77° - 98.6°)	

Note: The above skin temperatures have not been evaluated for correlation to core temperatures.

4.3 Physical Components

4.3.1 ViSi Mobile Monitor

ViSi Mobile Monitor		
Physical Characteristics	Dimensions	2.59 cm H x 4.85 cm W x 9.35 cm L 1.02 in. H x 1.91 in. W x 3.68 in. L exclusive of connectors and Wrist Cradle
	Weight	110 g / 3.92 oz
Monitor	Display	OLED, 160 x 128 pixels, full color
	Audio	Alarm annunciation, QRS, self-test
	Waveforms	One waveform, user selectable Aspect Ratio: 0.4 Sec/mV Scaled equivalent to 25 mm/sec sweep speed Respiration waveform scaled equivalent to 6.25 mm/sec sweep speed
Battery	Operating Time	> 12 hours
	Fuel Charge Display	Battery Symbol Charge Level with Full Indication
	Charge Time	Less than 4 hours
	Battery Type	Li-Ion, 3.7 V., 2000 mAh, single cell
	Maximum Temperature	45°C / 113°F Refer to IEC 60601-1:2005 (Section 11)
Cleaning / Disinfecting	Liquid Ingress Rating	IPX7 During cleaning cycle only, not during monitoring
	Solutions / Compounds	 ≤70% Isopropyl alcohol (IPA) Detergent (Alconox)

Wireless Communications / Radio

Wireless Communications		
Frequency	2.412 - 2.462 GHz	
Protocol	802.11 b/g/n	
Modulation	DSSS, OFDM, DBPSK, DQPSK, CCK, 16-QAM and 64-QAM	
Security	WPA2 / PSK, AES	
Power Output (max)	802.11 b: 15.8 dBm (38.3 mW)	
	802.11 g: 12.9 dBm (19.5 mW)	
	802.11 n: 11.8 dBm (15.1 mW)	
Data Throughput	< 30 KBps	

Physical Components



Other RF radiating devices (such as high powered RFID readers and Bluetooth devices) that are in close proximity with the ViSi Mobile Monitor may interfere with the Monitor's wireless communications. During such interference, the Monitor continues to monitor and will alarm locally. If wireless communication is affected when using the Monitor in close proximity with another RF radiating device, move the other device away from the Monitor or discontinue use of the other device. If you have any concerns regarding a cyber security breach or vulnerability, contact Sotera Wireless, Inc. or an authorized Sotera Wireless, Inc. representative in your area.

Mode Plugs

Mode Plugs	
Shipping Plug	Turns device off completely
Locking Plug	Secures Monitor into Wrist Cradle
Bio Med Mode ^a	Enables configuration and test functions

a. The Bio Med Mode is only available to hospital Bio Meds.

Physical Components

4.3.2 ViSi Mobile Chest Sensor

ViSi Mobile Chest Sensor			
Mechanical	Complies with EC53		
Weight (5 lead-wire / 3 lead-wire)	72 g / 62 g (2.54 oz. / 2.19 oz.)		
Operating Temperature	0 - 40°C / 32°F - 104°F Refer to IEC 60601-1:2005 (Section 11)		
Cleaning / Disinfecting	Liquid Ingress Rating IPX7 During cleaning cycle only, not during monitoring		
	Solutions / Compounds	≤70% Isopropyl alcohol (IPA) Detergent (Alconox)	

4.3.3 ViSi Mobile Cuff Module

ViSi Mobile Cuff Module		
Physical Characteristics	Dimensions	3.10 cm H x 4.85 cm W x 12.19 cm L (1.22 in. H x 1.91 in. W x 4.80 in. L) exclusive of cable
	Weight	157 g (5.54 oz)
Battery	Operating Time	> 30 cuff inflations or 24 hrs, whichever occurs first
	Charge Display Status	Eight LEDs: Six levels of Green, Yellow, Red
	Charge Time	< 4 hours
	Battery Type	Battery Pack, Li-Ion, 2000 mAh
	Maximum Temperature	45°C / 113°F Refer to IEC 60601-1:2005 (Section 11)
Cuff Sizes	Small	20 – 26
Arm Circumference (cm)	Medium	25 – 34
	Medium+	25 – 34
	Large	32 – 43
	Large+	32 – 43
Cleaning / Disinfecting	Liquid Ingress Rating	IPX0
	Solutions / Compounds	 ≤70% Isopropyl alcohol (IPA) Detergent (Alconox)



When the ViSi Mobile Cuff Module is connected to the other ViSi Mobile Components, the entire system has an ingress protection rating of IPX0.

Physical Components

4.3.4 ViSi Mobile Thumb Sensor

ViSi Mobile Thumb Sensor		
Cleaning / Disinfecting	Liquid Ingress Rating	IPX7 During cleaning cycle only, not during monitoring
	Solutions / Compounds	≤70% Isopropyl alcohol (IPA) Detergent (Alconox)

4.3.5 ViSi Mobile Charger - 8 Bay

ViSi Mobile Charger				
Physical Characteristics	Dimensions	7.7 cm x 46.3 cm x 5.9 cm (3.0 in x 18.2 in x 2.3 in)		
	Weight	0.7 kg (1.5 lb)		
AC Mains	AC Line Voltage	100-240 V, 50-60 Hz		
	Power (all bays charging)	75 W		
Cleaning / Disinfecting	Liquid Ingress Rating	IPX0		
	Solutions / Compounds	≤70% Isopropyl alcohol (IPA) Detergent (Alconox)		

4.3.6 ViSi Mobile Charger - 2 Bay

ViSi Mobile Charger				
Physical Characteristics	Dimensions	7.7 cm x 12.9 cm x 5.9 cm (3.0 in x 5.1 in x 2.3 in)		
	Weight	0.25 kg (0.6 lb)		
AC Mains	AC Line Voltage	100-240 V, 50-60 Hz		
	Power (all bays charging)	30 W		
Cleaning / Disinfecting	Liquid Ingress Rating	IPX0		
	Solutions / Compounds	≤70% Isopropyl alcohol (IPA) Detergent (Alconox)		

4.3.7 ViSi Mobile Power Pack (Optional Accessory)

ViSi Power Pack		
Physical Characteristics	Dimensions	3.13 cm H x 4.87 cm W x 12.19 cm L (1.23 in. H x 1.91 in. W x 4.80 in. L) Cable Length 3 to 5 ft.
	Weight	172 g (6.07 oz.)
Battery	Operating Time	minimum 24 hrs
	Charge Display Status	Eight LEDs: Six levels of Green, Yellow, Red
	Charge Time	< 6 hours
	Battery Type	Battery Pack, Li-Ion, 2000 mAh
	Maximum Temperature	50°C / 122°F Refer to IEC 60601-1:2005 (Section 11 for equipment not intended to contact patient)
Cleaning / Disinfecting	Liquid Ingress Rating	IPX0
	Solutions / Compounds	 ≤70% Isopropyl alcohol (IPA) Detergent (Alconox)

ViSi Power Pack Cradle

ViSi Power Pack Cradle				
Physical Characteristics	Dimensions	4.87 cm H x 9.5 cm W x 10.0 cm L (1.91 in H x 3.74 in W x 3.93 in L)		
	Weight	Without clamp: 91.3 g (3.22 oz.)		
		With clamp 0.53 kg (1.17 lb.)		
Cleaning / Disinfecting	Liquid Ingress Rating	IPX0		
	Solutions / Compounds	 ≤70% Isopropyl alcohol (IPA) Detergent (Alconox) 		

Physical Components

4.3.8 ViSi Mobile Appliance

ViSi Mobile Appliance	
Server Configuration	Single 1u, redundant hardware and internal RAID 10, dedicated hardware.
Processor	Single Intel Xeon 5620 2.4 GHz (or equivalent CPU) 8 GB memory
Storage	Server contains at a minimum 4 x 500 GB 7200 RPM hard drives in RAID 10 array
Operating System	Note: SUSE Linux Enterprise Server (Version 11, Patch Level 2)
Network Requirements	Static IP address or DHCP reservation required Multicast configuration on network backbone devices
Dimensions (Single Appliance, may vary)	H: 43.0 cm x W: 43.4 cm x L: 62.7 cm (w/o ear, w/o bezel) H: 1.7 in x W: 17.1 in x L: 24.7 in
Weight (Single Appliance)	35.02 lb (15.9 kg) (Maximum configuration weight)
Power Requirements (Single Appliance)	100-240 VAC, 50-60 Hz, 7 A - 3.5 A w/ redundant power supply
Backup Power Requirement (Full System)	Customer supplied Uninterruptable Power Supply and Hospital Emergency Power recommended.

In the ViSi Mobile Monitoring System, data is captured in the ViSi Mobile Appliance, which acts as an enterprise hub. The Appliance is dedicated hardware installed in the IT datacenter for secure network connectivity and emergency power backup. For more information on the ViSi Mobile Appliance, see the ViSi Mobile Monitoring System Technical Reference Manual.

4.3.9 ViSi Mobile Remote Viewer

ViSi Mobile Remote Viewer (Desk	ViSi Mobile Remote Viewer (Desktop PC with Touchscreen Display)				
No. of Patients per Remote Viewer	Maximum 32				
Display	23 in display / 1920 x 1080 resolution (screen is touch sensitive to issue commands alternative to mouse/keyboard)				
Processor	Intel i5 2400 CPU 4 Core 3.10 GHz 4 GB Memory				
Storage	One 500 GB 7200 RPM SATA				
Operating Systems	Microsoft® Windows® 7 Professional (version 6.1) x64 Bit SP1				
Network Requirements	Ethernet Connection, DHCP				
Dimensions	H: 45.0 cm x W: 58.5 cm x D: 10.3 cm H: 17.7 in x W: 23.0 in x D: 4.1 in				
Weight	26.7 lb (12.1 kg)				
Power Requirements	AC/DC Adapter Input: 100-240 V ~3.5 A, 50-60 Hz Output to Viewer: 19.5 V / 11.8 A				
Backup Power Requirement	Customer supplied Uninterruptable Power Supply and Hospital Emergency Power recommended.				

Note: Sotera Wireless, Inc. recommends installation of Trend Micro anti-virus software on Windows platforms. Anti-virus software is not installed on the ViSi Mobile Monitor.

Note: For printing capability, Sotera Wireless, Inc. recommends connecting a printer directly to the ViSi Mobile Remote Viewer or to an in-network printer via an IP address. Sotera Wireless, Inc. does not support additional configurations.

4.3.10 Customer Network

Wireless Network	
Wireless Network Standard	IEEE 802.11b/g/n
Recommended Channels	1, 6, 11
Network Latency	< 150 ms
Wireless Network Security Support	WPA2-PSK
Minimum Receiver Sensitivity	-65 dBm (edge coverage)
Wireless access point cell overlap	15-20%
Signal-to-Noise Ratio	≥25 dB
Packet loss	≤6%
SSID	Dedicated or shared with other medical devices

Wired Network	
Appliance (Server)	Requires static IP Address
Network availability	>99.9%

4.4 Alarms / Alerts Annunciation

Note: An "Annunciation Delay" is the time that an alarm system deliberately delays the alarm annunciation (audibly and visually) to ensure clinical relevance of the detected alarming condition. Within the tables below, see column "Annunciation Delay" for the pre-defined periods of time.

4.4.1 Physiological Alarms (Alarms)

Visual Display

The following table outlines the visual display when alarms are in progress:

Severity	Indicator Attributes	Toggle / Flash Speed	Duty Cycle
High Priority	Red	1.5 Hz	50% ON
Life-Threatening Priority	Red / White	1.5 Hz	50% ON

Audio Tones

The following table outlines the audio tones when alarms are in progress:

Severity	Melody ^a	Volum e [dB]	Frequency (f _o) [Hz]	Duration (t _d) [ms]	Spacing (t _s) [ms]	5th-6th [s]	Inter-Burst (t _b) [s]
Life Threatening	b5.b5.b5b5.b5	78	987.767	100	50	0.35	2.5
High	b5.b5.b5b5.b5	78	987.767	200	100	0.35	5

a. Melodies are defined as musical notes.

Alarm Limits and Delays (factory default settings).

Vital Sign	Lower Limit		Upper Limit		Annunciation Delay ^a
	Care Unit	Patient	Patient	Care Unit	(seconds)
Critical Low HR (BPM)	18	18	N/A	N/A	5
Heart Rate (BPM)	30	30	150	200	5
Pulse Rate (BPM)	30	30	150	200	30
BP Systolic (mmHg)	70	OFF	190	240	120
BP Diastolic (mmHg)	40	OFF	OFF	150	120
BP MAP (mmHg)	60	65	OFF	170	90
Respiration (BR/MIN)	4	4	35	40	120
SpO ₂ (%)	85	85	N/A	N/A	60
Skin Temperature	N/A	N/A	N/A	N/A	N/A

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Alarms / Alerts Annunciation

a. When measuring blood pressure as a 1-time measurement or at automatic intervals, there will be no annunciation delay.

Alarms / Alerts Annunciation

Battery Alarms

No Pulse Detected Alarms	Limit	Annunciation Delay
When Thumb Sensor is primary source	No Pulse	No delay
When Cuff Module is primary source	No Pulse	No delay

	Battery Alarms	Limit	Annunciation Delay
ır	Monitoring Mode	45°C (113°F)	No delay
Monitor	In the Charger	45°C (113°F)	No delay
M	Not monitoring / Not in the Charger	45°C (113°F)	No delay
e	Connected to the Monitor	45°C (113°F)	No delay
Cuff Module	In the Charger	45°C (113°F)	No delay
Z	Not monitoring / Not in the Charger	45°C (113°F)	No delay
ıck	Connected to the Monitor	50°C (122°F)	No delay
Power Pack	In the Charger	50°C (122°F)	No delay
Pow	Not monitoring / Not in the Charger	50°C (122°F)	No delay

4.4.2 Equipment Alarms (Alerts)

Visual Display

The following table outlines the visual display when alerts are in progress:

Severity	Indicator Attributes	Toggle / Flash Speed	Duty Cycle
All Severities	Cyan (Blue)	Constant (ON)	100% ON

Audio Tones

The following table outlines the audio tones when alerts are in progress:

Severity	Melody ^a	Volume [dB]	Frequency (f _o) [Hz]	Duration (t _d) [ms]	Spacing (t _s) [ms]	Inter-Burst (t _b) [s]
High	e5.c5	68/63	659.255, 523.251	250	250	15

a. Melodies are defined as musical notes.

Note: There are no audio tones associated with low severity alerts.

Alarm Limits and Delays (factory default settings)

Chest Sensor Alerts	Limit(if applicable)	Audible Alert	Annunciation Delay
ECG Lead Failure	N/A	No	No delay
All ECG Lead Failure	N/A	No	No delay
Chest Sensor Disconnected	N/A	No	No delay
General Fault Detected	N/A	No	No delay
Multiple Connections	N/A	No	No delay
Temperature Sensor Fault	N/A	No	No delay
Accelerometer Fault - Chest Module	N/A	No	No delay
Accelerometer Fault - Upper Arm	N/A	No	No delay

Thumb Sensor Alerts	Limit (if applicable)	Audible Alert	Annunciation Delay (in seconds)
Thumb Sensor Off	N/A	No	< 30
Thumb Sensor Disconnected	N/A	No	No delay

Cuff Module Alerts	Limit (if applicable)	Audible Alert	Annunciation Delay (in seconds)
Low Battery	4% to 10%	No	No delay
Battery Empty	< 4%	No	No delay

Alarms / Alerts Annunciation

Cuff Module Alerts	Limit (if applicable) Audible Alert		Annunciation Delay (in seconds)
Check Cuff	N/A	No	No delay
Cuff Occluded	N/A	No	No delay
NIBP Unobtainable	N/A	No	No delay
Invalid Software Loaded	N/A	No	No delay
Pressure Accuracy Fault	N/A	No	No delay
General Fault Detected	N/A	No	No delay
Pressure Exceeded	300mmHg	Yes	No delay
Multiple Connections	N/A	No	No delay

cNIBP Alerts	Limit (if applicable)	Audible Alert	Annunciation Delay (in seconds)
Calibration Failed	N/A	N/A	No delay
Calibrate cNIBP	N/A	N/A	No delay
Hold Still	N/A	N/A	No delay

Wrist Monitor Alerts	Limit (if applicable)	Audible Alert	Annunciation Delay (in seconds)
Calibrate cNIBP	N/A	N/A	No delay
Low Battery	3 hours	No	No delay
Critical Low Battery	1 hour	No	No delay
Too Low to Monitor	10 minutes	No	No delay
Invalid Plug Connected	N/A	Yes	No delay
Audio System Failure	N/A	No	No delay
Wireless Radio Failure	N/A	No	No delay
All Sensors Disconnected	N/A	No	No delay
Accelerometer Failure	N/A	No	No delay
Shock Hazard	N/A	Yes	No delay
Patient Tampering (number of incorrect pin code entries)	5 invalid pin codes	No	No delay

ViSi Power Pack Alerts	Description of Annunciation	Audible Alert	Annunciation Delay (in seconds)
Power Pack Connected	1 Beep	Yes	No delay
Power Pack Disconnected	1 Beep	Yes	No delay
Power Pack Low Battery	Red LED Flashes (< 4% charge) Yellow LED Flashes (4%-10% charge)	No	No delay

ViSi Power Pack Alerts	Description of Annunciation	Audible Alert	Annunciation Delay (in seconds)
Battery Temp. Exceeds Limit	Red LED Solid and Continuous Beep Tone	Yes	No delay
Battery Current. Exceeds Limit	Red LED Solid and Continuous Beep Tone	Yes	No delay
Battery Pack Fault	Message on ViSi Monitor	Beep/Buzz on Power Pack ONLY	No delay

4.5 Environmental Conditions

Environmental Conditions for all ViSi Mobile Components (Monitor, Cuff Module, Chest Sensor, Cuff, Thumb Sensor, Power Pack)					
Condition	Storage (Packaged / Unpacked)	Operating (Unpackaged)			
Temperature	-20°C to +55°C (50°C for NIBP) -4°F to +131°F (122°F for NIBP)	0°C to +40°C / 32°F to +122°F Battery Charger: 0°C to +40°C			
Humidity	15% to 95% non-condensing (90% for NIBP)	10% to 95% non-condensing (90% for NIBP) (15% to 95% non-condensing for Power Pack)			
Atmospheric Pressure Range	107 kPa to 50 kPa 803 mmHg to 375 mmHg 1.06 atm to 0.49 atm	107 kPa to 70 kPa 803 mmHg to 525 mmHg 1.06 atm to 0.69 atm			



The ViSi Mobile Monitoring System may not perform to specification if stored or shipped outside the specified temperature range.

Compliances

4.6 Compliances

Observe any national regulations on the qualification of the testing personnel and suitable measuring and testing facilities. See "User/Preventative Maintenance" on page 105. for a list of required tests.

4.6.1 Federal Communications Commission (FCC)

The equipment device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) This device must accept any interference received including interference that may cause undesired operation.

Changes or modifications not expressly approved by Sotera Wireless, Inc. could void the user's authority to operate the equipment. Manufacturer is not responsible for any radio or TV interference caused by unauthorized modifications to this equipment.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna
- Increase the separation between the equipment and receiver
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected
- Consult the dealer or an experienced radio/TV technician for help

This device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes : (1) l'appareil ne doit pas produire de brouillage, et (2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

Class B digital device notice / "CAN ICES-3 (B)/NMB-3(B)".

This equipment complies with the FCC/IC radiation exposure limits set fourth for portable transmitting devices operation in a controlled environment. End users must follow the specific operating instructions to satisfy RF exposure compliance.

The equipment should only be used where there is normally at least 22.651mm separation between the antenna and all person/user.

This transmitter must not be co-located or operated in conjunction with any other antenna or transmitter.

Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment.

Compliances

4.6.2 Electromagnetic Compatibility (EMC) Specifications

Take special precautions regarding electromagnetic compatibility (EMC) when using medical electrical equipment. Operate your monitoring equipment according to the EMC information provided in this manual. Portable and mobile radio frequency (RF) communications equipment can affect medical electrical equipment.



Consult your Biomed department or vendors for assistance in identifying EMC compliance status of other medical devices when using the ViSi Mobile Monitoring System or Power Pack.

Accessories Compliant with EMC Standards

All accessories (e.g. ViSi Mobile Charger) comply with either IEC 60601-1-2 or IEC 60950-1.



Using accessories other than those specified may result in increased electromagnetic emission or decreased electromagnetic immunity of the monitoring equipment.

4.6.3 Electromagnetic Emissions

The ViSi Mobile Monitor is suitable for use in the electromagnetic environment specified in the table below. Ensure that the Monitor is used in such an environment.

Emissions Test	Compliance	Avoiding Electromagnetic Interference
Radio Frequency (RF) emissions	Group 1	The ViSi Mobile Monitor uses RF energy only for its internal function ^a . Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The ViSi Mobile Monitor is suitable for use in all
Harmonic emissions IEC 61000-3-2	N/A	establishments other than domestic and those directly connected to the public low-voltage
Voltage fluctuations IEC 61000-3-3	N/A	supply network that supplies buildings used for domestic purposes.

a. The battery operated ViSi Mobile Monitor contains a 2.4 GHz DSSS transmitter for the purpose of wireless communication. The radio is excluded from the EMC requirements of IEC 60601-1-2, but should be considered when addressing possible interference issues between this and other devices.

Compliances

4.6.4 Electromagnetic Immunity

The ViSi Mobile Monitor is suitable for use in specified electromagnetic environments. The user must ensure that it is used in the appropriate environment as described below.

Immunity Test	IEC 60601-1-2		Electromagnetic
immumity Test	Test Level	Compliance Level	Environment Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient / burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical medical and/or hospital environment.
Surge IEC61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical medical
Voltage dips, short interruptions and	<5% UT (>95% dip in UT) for 0.5 cycles	<5% UT (>95% dip in UT) for 0.5 cycles	and/or hospital environment.
voltage variations on power supply	40% UT (60% dip in UT) for 5 cycles	40% UT (60% dip in UT) for 5 cycles	
input lines IEC 61000-4-11	70% UT (30% dip in UT) for 25 cycles	70% UT (30% dip in UT) for 25 cycles	
	<5% UT (>95% dip in UT) for 5 sec	<5% UT (>95% dip in UT) for 5 sec	
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical hospital environment.

In the above table, UT (Unit in Test) is the ViSi Mobile Monitoring System.

Compliances

4.6.5 Recommended Separation Distance



The ViSi Mobile Monitor may be temporarily interrupted by UHF RFID Systems (860-960MHz).



2-way radios may cause waveform distortion when placed within 1 foot of the ViSi Mobile Monitor.



Some brands of television may cause temporary waveform distortion and data loss when placed within 6 feet of the ViSi Mobile Monitor.

Portable and mobile RF communications equipment should be used no closer to any part of the ViSi Mobile Monitor, including cables, than the recommended separation distance calculated from the equation appropriate for the frequency of the transmitter.

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.

Interference may occur in the vicinity of equipment marked with this symbol:



In the following table, P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).

Immunity Test	IEC 60601-1-2 Test Level	ViSi Mobile Monitoring System Compliance Level	Electromagnetic Environment Guidance
Conducted RF IEC 61000-4-6	3 V _{RMS} 150 kHz to 80 MHz	3 V _{RMS}	Recommended separation distance: $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	Recommended separation distance: 80 MHz to 800 MHz 80 MHz to 800 MHz $d = 3.5\sqrt{P}$ 800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$ 2.0 to 2.3 GHz for short radio $d = 7.0\sqrt{P}$

Field strengths from fixed transmitters, such as base stations for radio (cellular, cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To access the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ViSi Mobile Monitor is used exceeds the applicable RF compliance level above, the Monitor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Monitor.

These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

From Portable and Mobile RF Communication Equipment

The ViSi Mobile Monitor is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the Monitor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment and the Monitor as recommended below, according to the maximum output power of the communications equipment.

In the following table, P is the maximum power output rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).

Frequency	150 kHZ to 80 MHz		80 MHz to 800 MHz		800 MHz to 2.5 GHz	
Equation	$\mathbf{d} = 1.2\sqrt{\mathbf{P}}$		d=1.2√P		d=2.3√P	
Rated max. output	Separation Distance		eparation Distance Separation Distance		Separation Distance	
power of transmitter	(m)	(ft)	(m)	(ft)	(m)	(ft)
0.01 W	0.1	0.4	0.1	0.4	0.2	0.8
0.1 W	0.4	1.2	0.4	1.2	0.7	2.4
1 W	1.3	3.9	1.3	3.9	2.3	7.5
10 W	3.8	12.4	3.8	12.4	7.3	23.9
100 W	12.0	39.4	12.0	39.4	23.0	75.5

Electrosurgery Interference/Defibrillation/Electrostatic Discharge

The equipment returns to the previous operating mode within 10 seconds without loss of any stored data. Measurement accuracy may be temporarily decreased while performing electrosurgery or defibrillation. This does not affect patient or equipment safety. Do not expose the equipment to x-ray or strong magnetic fields (MRI).

Fast Transients/Bursts

The equipment will return to the previous operating mode within 30 seconds without loss of any stored data.

Compliances

4.6.6 Standards

Agency Compliances

- CAN/CSA C22.2 No 60601-1, Part 1: General requirements for basic safety and essential performance
- IEC 60601-1:2005 Medical electrical equipment Part 1: General requirements for safety (EN 60601-1:2006)
- IEC 60601-1-2:2007, Med. Elect. Equipment Part 1-2: General requirements for safety Collateral standard: EMC Reg. and tests.
- IEC 60601-1-6:2010, Medical electrical equipment Part 1-6: General requirements Collateral standard: Usability.
- IEC 60601-1-8:2012, Medical electrical equipment Part 1-8: Gen. req. Col. Std. Gen. requirements, tests and guidance for alarm systems
- IEC 60601-2-27:2011, Medical electrical equipment, Part 2-27: Particular requirements or the safety, including essential performance, of ECG monitoring equipment (except 208.6.6.2.103).
- IEC 80601-2-30:2009, Medical electrical equipment Part 2-30: Particular requirements for the safety, including essential performance, of auto. cycling non-invasive BP monitoring equipment.
- IEC 60601-2-49:2011, Medical electrical equipment Part 2-49: Particular requirements for the basic safety and essential performance of multi-function patient monitoring equipment.
- ISO 80601-2-61:2011, Medical electrical equipment Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use.
- IEC 62304:2006, Medical device software Software life cycle processes
- IEC 62366:2007, Medical devices Application of usability engineering to medical devices.

4.7 Wireless Network Risk Mitigation

Reference: ISO 80001-1

ViSi Mobile System utilizes the Responsible Organization's wireless IT network to communicate between individual ViSi Mobile Monitors connected to patients and the ViSi Appliance. Physiologic data and alarms originating from the ViSi Mobile Monitors are transmitted over the IT network to the ViSi Mobile Remote Viewer where supplemental alarm notification occurs. Reliability of the IT network is essential in ensuring the supplementary alarm notification meets the intended use.



Other RF radiating devices (such as high powered RFID readers and Bluetooth devices) that are in close proximity with the ViSi Mobile Monitor may interfere with the Monitor's wireless communications. During such interference, the Monitor continues to monitor and will alarm locally. If wireless communication is affected when using the Monitor in close proximity with another RF radiating device, move the other device away from the Monitor or discontinue use of the other device. If you have any concerns regarding a cyber security breach or vulnerability, contact Sotera Wireless, Inc. or an authorized Sotera Wireless, Inc. representative in your area.



Perform a risk assessment and verification before implementing a change or modification to the IT infrastructure. Changes to IT network configurations can compromise continuous vital signs monitoring and alarm delivery. on page 12

4.7.1 Risk Analysis Summary

- The ViSi Mobile Monitors are the source of all alarms and alerts.
- The ViSi Mobile Remote Viewer provides a supplemental alarm notification. When connectivity is present audio alarms are deferred to the ViSi Mobile Remote Viewer.
- In the event that network connectivity is lost, all audio alarms are annunciated at the ViSi Mobile Monitors. A connectivity lost alert is annunciated at the ViSi Mobile Remote Viewer.

4.7.2 Residual Risks

Loss of network connectivity will result in failure in supplemental alarm notification to the ViSi Appliance and ViSi Mobile Remote Viewer. Management of this risk is the responsibility of the Responsible Organization for the IT Network. This risk is minimized with the following mitigations:

Sotera Responsibilities

- Sotera Inc network assessment prior to installation.
- Sotera Inc verification that the Responsible Organization network meets ViSi Mobile System connectivity requirements at the time of installation.
- Hand over protocol with all settings/configurations as installed and configured (Training)

Responsible Organization Responsibilities

- Conduct a risk assessment of the IT Network prior to installation and mitigate technical risk.
- Maintain backup and emergency power resources for ViSi System network components.
- Maintain network configuration post installation of the ViSi Mobile System.

Wireless Network Risk Mitigation

Notify Sotera Wireless, Inc. prior to making modifications to the network, including configuration changes that could potentially compromise the IT Network as verified at the initial installation of the ViSi System.

For support contact Sotera Wireless, Inc. or an authorized Sotera Wireless, Inc. representative in your area.

- Notes -



Product Modes

5.1 Introduction

Customer site Bio Meds will be able to access ViSi Mobile's different Product Modes using an 8-digit PIN. The 8-digit PIN is available upon request by calling Sotera Wireless' Customer Service located page 103.

Bio Meds will be the only ones who will be able to access the different Product Modes.



Bio Meds must complete training by Sotera Wireless, Inc. before utilizing any of these functions.

5.2 Monitoring/Non-Monitoring Modes

In order to access Product Modes, the Monitor must be in "Non-Monitoring" Mode.

When the ViSi Mobile Monitor is in "Non-Monitoring" Mode, a "gear" symbol wll be displayed in the upper right side of the Monitor.

	Enabled	Disabled
Non-Monitoring Mode	©	B



Monitoring Mode



Non-Monitoring Mode



Non-Monitoring Mode - Enabled Battery Charged



Non-Monitoring Mode - Disabled Battery Critically Low

Note: When the Monitor's battery becomes critically low, the "Modes" and "Device Swap" menu options become disabled.

5.3 Bio Med Mode

The "Bio Med" Mode allows the Bio Med to access select Monitor settings.

	Enabled	Disabled
Bio Med Mode		4

Note: The ViSi Mobile Monitor must be in "Non-Monitoring" Mode in order to access this funtion. Bio-Med must use the 8-digit PIN code given by Sotera Wireless' Customer Service.

Accessing Bio Med Mode

- 1. Touch the "Mode" symbol.
- 2. Select "Bio Med" symbol.
- 3. Enter "Bio Med" 8-digit PIN.
- 4. If the "Back" button is selected, the screen will revert back to the "Select Mode" screen.
- 5. Once the first number of the PIN are entered, the "Back" button will be replaced with the "Cancel" button.
- 6. As additional numbers are added, a white dot will appear for each numeric entered.
- 7. If the "Cancel" button is pressed, all already entered numbers will be erased and the "Cancel" button will revert back to the "Back" button.
- 8. Once a correct 8-digit PIN has been entered and the "Confirm" button selected, the "Bio Med" screen will appear.
- 9. If an incorrect 8-digit PIN has been entered, the screen will flash red for approximately three seconds. Numerics page will be displayed to try again.



The "Bio Med" Mode session will end once any one of the following occurs:

- a. The "Lock" button is touched.
- b. A thumb sensor is connected to the Monitor.
- c. The Monitor is placed into a charger.



Bio Med Mode allows access to erase Network Configurations on the Monitor. If Network Configurations accidentally get erased, the Monitor will have to be returned to Sotera Wireless, Inc.to be reloaded again. Do NOT erase Network Configurations.

Enable/Disable Skin Temperature

5.4 Enable/Disable Skin Temperature

The Skin Temperature Vital Sign can be enabled or disabled while in "Bio Med" Mode. This setting can only be changed for stand-alone Monitors. All networked Monitors will become configured by the .XML file once the Monitors re-connect to the network.

Case 1:22-cv-01378-MN-JLH Document 175-1 Filed 07/14/23 Page 95 of 561 PageID #: 10674 Enable/Disable Skin Temperature

- Notes -

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Enable/Disable Skin Temperature



6. Updating Remote Viewer Settings

6.1 Introduction

Certain settings on the ViSi Remote Viewer can be changed by the hospital's Bio Med.



Bio Meds must complete training by Sotera Wireless, Inc. before utilizing any of these functions.

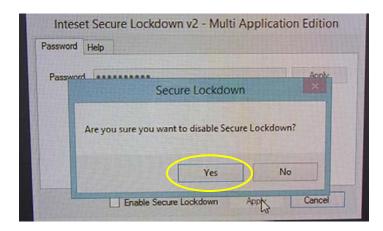
6.2 Disable Secure Lockdown

To disble Secure Lockdown:

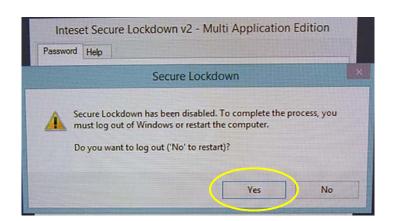
- 1. Simultaneously press "Alt, Shift and S" keys on the keyboard
- 2. Enter "s0t3r@9444" for the "Password"
- 3. Un-check the "Enable Secure Lockdown" box and Click "Apply"



4. When asked "Are you sure you want to disable Secure Lockdown", Click "Yes"



5. When asked "Do you want to log out (No to restart)?" Click "Yes"



6.3 Disable (Wireless Settings) WLAN NIC Adaptor

To disable the Wireless Settings/WLAN NIC Adaptor:

1. Locate the "Network 3 Internet Access" icon on the tool bar

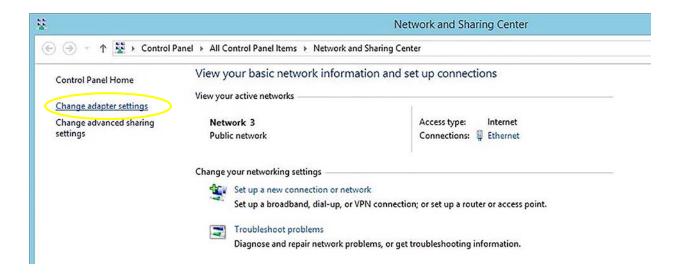


2. Click "Open Network and Sharing Center"

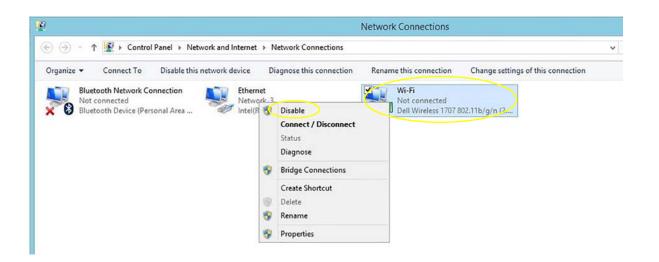


Configure NTP Client

3. Click "Change adapter settings" link on the left



- 4. Right Click on the adapter for the wireless NIC
- 5. Click "Disable" in drop down menu



6.4 Configure NTP Client

To configure the NTP Client:

- 1. Locate the NTP client application in the hidden icon notification area in the lower right hand corner of screen
- 2. Click the "Show Hidden Icon" arrow

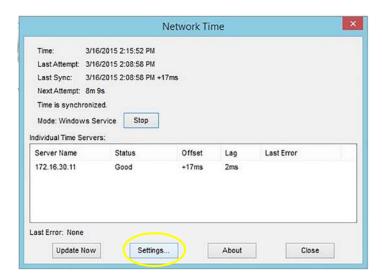


3. Click on "Network Time Synchronization"

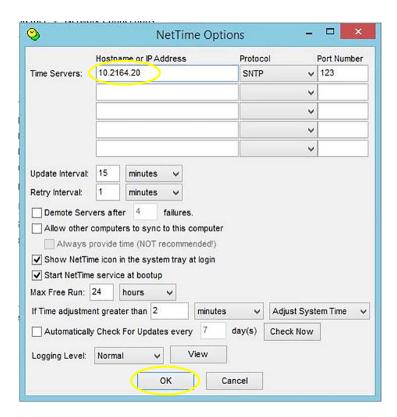


4. Click the "Settings" button along the bottom of display box

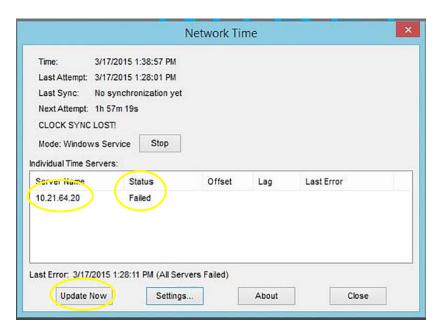
Configure NTP Client



- 5. Enter "IP Address" in first line of "Time Servers"
- 6. Click "OK" on the bottom of display



7. Click "Update Now" on the bottom of the dislpay box to test connectivity

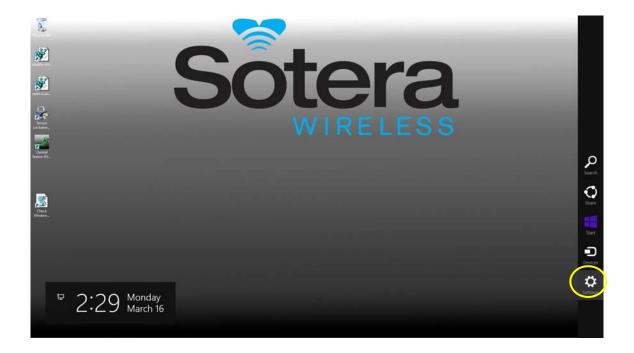


Note: If status reads "Failed", the IP Address is incorrect. Steps in Section 6.4Configure NTP Client will need to be performed again until Status is "Passed".

Disabling Synch with Network Time and Change Time Zone

6.5 Disabling Synch with Network Time and Change Time Zone

- 1. Locate "Settings" icon in lower right corner of screen
- 2. Click on the "Settings" icon

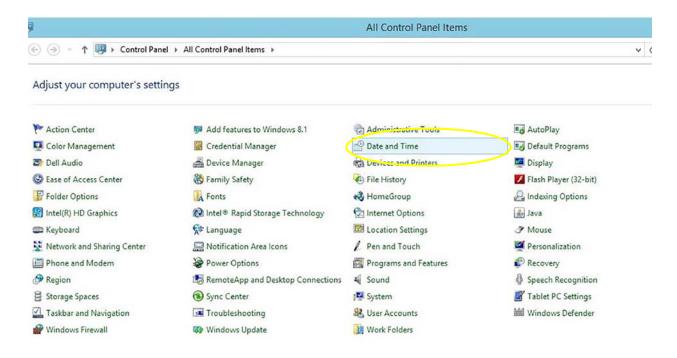


Disabling Synch with Network Time and Change

3. Click "Control Panel" on right side of screen.

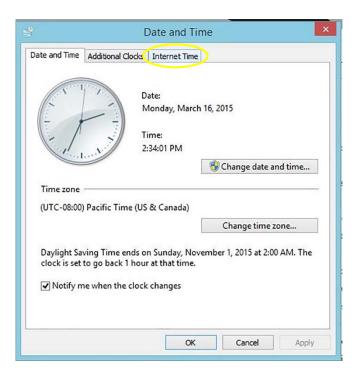


4. Click on "Date and Time" option

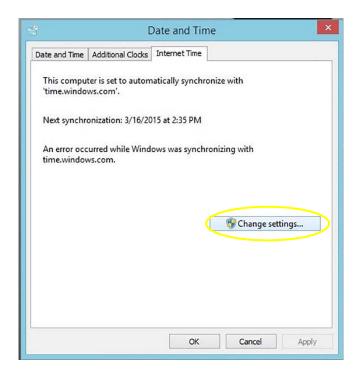


10685 Disabling Synch with Network Time and Change Time Zone

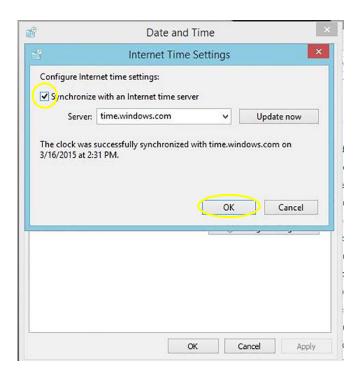
5. Click on the "Internet Time" Tab



6. Click on "Change settings..." button in the middle of display screen

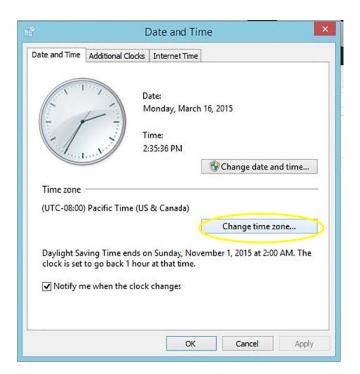


- 7. Un-check the "Synchronize with an Internet time server" box
- 8. Click "OK"

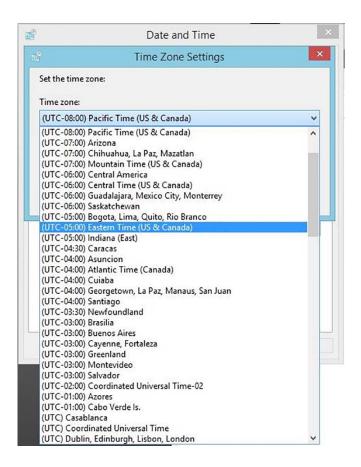


 $\begin{array}{c} 10687 \\ \textbf{Disabling Synch with Network Time and Change Time Zone} \end{array}$

9. Click "Change time zone" button

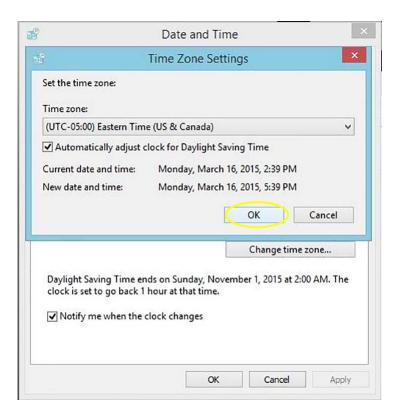


10. Use the drop down menu to select the desired time zone

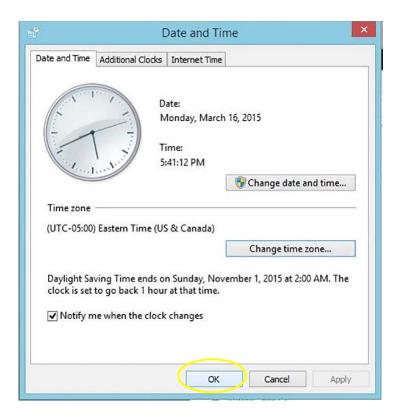


$\begin{array}{c} 10689 \\ \textbf{Disabling Synch with Network Time and Change Time Zone} \end{array}$

11. Click "OK" to accept desired "Time zone settings"



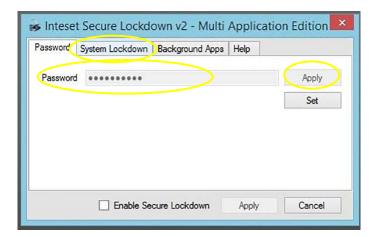
12. Click "OK" to confirm Time zone changes



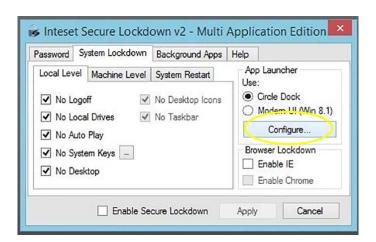
6.6 Configure Inteset Secure Lockdown v2

To configure Inteset Secure Lockdown v2 with the Server IP Address:

- 1. Simultaneously press "Alt, Shift and S" keys on the keyboard
- 2. Enter "s0t3r@9444" for the "Password"
- 3. Click "Apply" to the right of the "Password"
- 4. Click on the "System Lockdown" tab



5. Click "Configure" button



The Patient icon will now be displayed.

- 6. Right click on the "Patient" icon
- 7. The "Menu" drop down will apper; click "Item Settings" on the bottom of list



Update the IP Address.

- 8. Hightlight the "IP Address" under "Arguments" section for the "IP Address" that should be changed
- 9. Enter in the NEW "IP Address" by typing over the OLD highlighted "IP Address"
- 10. Click "Close"



Verify DHCP or Update Static IP Address



ONLY change the IP Address. Do not delete any other information in this section. Exit out of this display screen without saving if there is any doubt that any other information has been changed. Repeat step again to make the required change.

- 11. Access the menu by right clicking on the desktop
- 12. Select and click "Quit" to exit

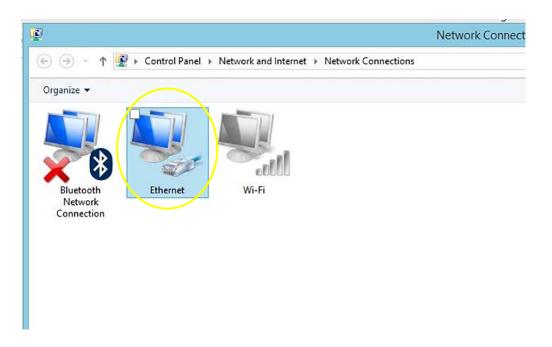


6.7 Verify DHCP or Update Static IP Address

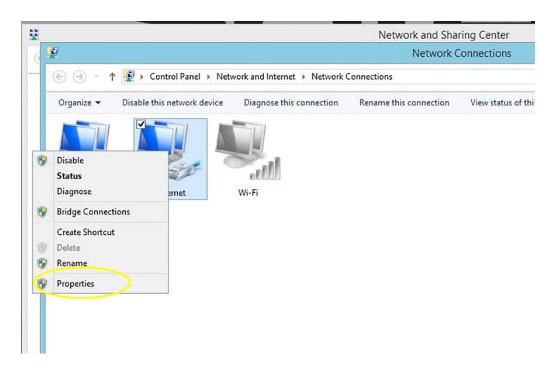
To verify the DHCP or update the Static IP Address:

Verify DHCP or Update Static IP Address

- 1. Access the "Network Connections" display (See steps 2.Click "Open Network and Sharing Center" on page 75 and 3.Click "Change adapter settings" link on the left on page 76)
- 2. Right Click on "Ethernet" icon



Click on "Properties"

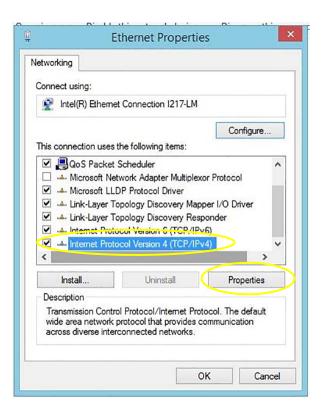


Ethernet Properties will now be displayed.

3. Select "Internet Protocol Version 4 (TCP/IPv4) in drop down

Verify DHCP or Update Static IP Address

4. Click "Properties"



Internet Protocol Version 4 (TCP/IPv4) will be displayed.

DHCP is the default setting and can be confirmed by checking the following:

- 1. "Obtain an IP Address automatically" radio button is selected
- 2. "Obtain DNS server address automatically" radio button is selected
- 3. Click "Cancel" after confirmation

If the Static IP Address needs to change:

- 1. Click "Use the following IP Address" radio button
- 2. Enter the "IP Address", "Subnet Mask", and "Default Gateway" in fields below that section
- 3. Click "Use the following DNS server addresses" radio button
- 4. Enter "Preferred DNS server" and/or "Alternate DNS server" addresses in fields below that section
- 5. Click "OK" after change



6.8 Change Hostname

To change the hostname:

- 1. Locate "This PC" icon on the desktop
- 2. Right click "This PC" icon to access the menu
- 3. Select "Properties"

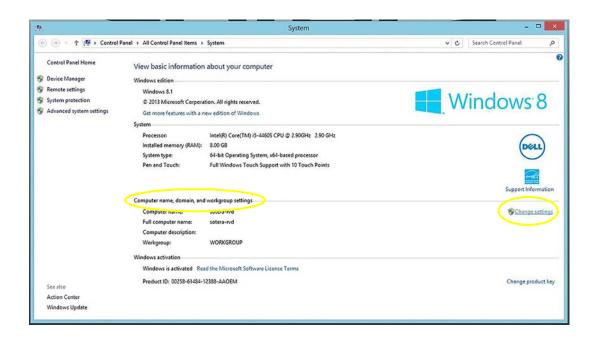


Change Hostname



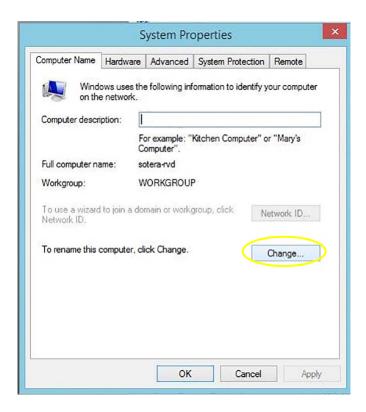
The "System" display page will come up.

- 1. Locate the "Computer name, domain and workgroup settings" section on page
- 2. Click the "Change settings" link to the right



The "System Properties" display page will come up.

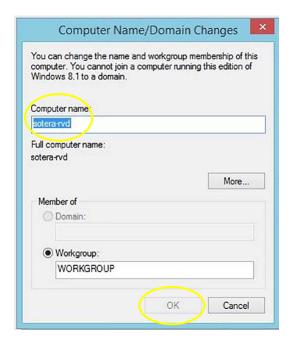
1. Click the "Change" button



The "Computer Name/Domain Changes" display page will come up.

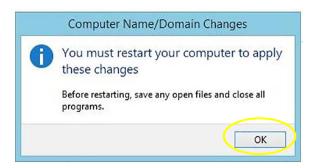
- 1. Enter new "Computer Name"
- 2. Click "OK"

Change Hostname



The "Computer Name/Domain Changes" Restart Computer prompt will pop-up.

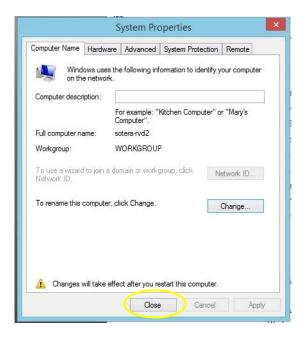
1. Click "OK" to restart computer for changes to apply



"System Properties" display will come up.

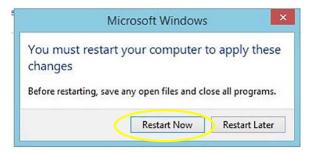
Disable-CTRL

1. Click "Close"



"Microsoft Windows" display will come up.

1. Click "Restart Now" for computer to restart and apply name change



Note: You must restart computer in order for changes to take effect.

6.9 Disable-CTRL

To disable CTRL:

- 1. Locate the "disable-ctrl" icon
- 2. Double click on the "disable-ctrl" icon



The first "Registry Editor" dialog box will now be displayed.

1. When asked "Are you sure you want to continue", Click "Yes"



The second "Registry Editor" dialog box will now be displayed.

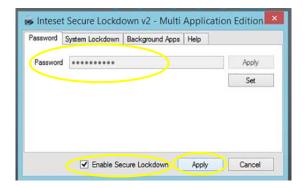
1. Click "OK" to the "The keys and values contained in C:\Sotera\disable-ctrl-and-del.reg have been successfully added to the registry" message displayed



6.10 Re-activate Secure Lockdown

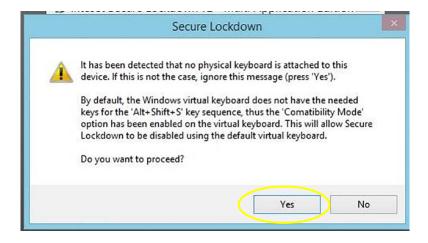
To enable Secure Lockdown again:

- 2. Simultaneously press "Alt, Shift and S" keys on the keyboard
- 3. Enter "s0t3r@9444" for the "Password"
- 4. Check the "Enable Secure Lockdown" box and Click "Apply"



A prompt indicating that "no physical keyboard is attached to the device..." will be displayed.

1. Click "Yes"



Next prompt will appear asking "Are you sure you want to enable Secure Lockdown".

Re-activate Secure Lockdown

1. Click "Yes"



Last prompt will appear asking "Do you want to log out".

1. Click "No" to restart the computer and complete the process



Note: You must restart computer in order for changes to take effect.

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Re-activate Secure Lockdown

- Notes -

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Re-activate Secure Lockdown



7. Troubleshooting

7.1 Introduction

Refer to the ViSi Mobile User Manual or contact Customer Service:

Toll-Free: +1-866-232-6126

International: +1-858-427-4620

Fax: +1-999-2487

E-mail: support@soterawireless.com

- Notes -



8. User/Preventative Maintenance

8.1 Introduction

This section of the manual outlines routine maintenance that should be performed by the user. The ViSi Mobile Monitoring System is designed for stable operation over long periods of time and, under normal circumstances, should not require technical maintenance beyond that described in this section.

8.2 Preventative Maintenance

All ViSi Mobile components are designed to internally calibrate each time they are used. Therefore, no routine calibration checks are required during routine preventative maintenance cycles. Routine testing of functionality/accuracy can be verified using standard electronic patient simulators and compared against the references in this manual.

Sotera Wireless, Inc. recommends preventative maintenance as follows:

Chest Sensor / Monitor	Visual inspections for mechanical abuse is recommended at a frequency consistent with use. Annual inspection is recommended but not required.
Cuff Module	Visual inspection and routine calibration checks against a known volume is recommended on an annual basis. The air filter should be replaced at this time. Calibration volume and replacement air filters can be purchased from Sotera Wireless, Inc. or the units can be returned to Sotera for a nominal fee.
SpO ₂ Sensor	The SpO ₂ sensor comes with a standard 3 month warranty. Actual life cycle duration is dependent on use and care. No preventative maintenance is required.
Optional ViSi Power Pack	Regular visual inspection for mechanical abuse is recommended at a frequency consistent with use. The ViSi Power Pack does not require calibration.

Note: Prior to any preventative or corrective service, ViSi Mobile components should be cleaned and disinfected. See below.

In the event any component needs to be returned to Sotera Wireless, Inc; contact the Sotera Wireless, Inc. Customer Service Department or the Sotera Wireless, Inc. representative in your area. Prior to shipping, ensure the returned components have been properly disinfected.



The ViSi Mobile Monitoring System components, including the ViSi Power Pack should only be serviced by Sotera Wireless, Inc. technicians or authorized service providers.

8.3 Cleaning and Disinfection

The ViSi Mobile Monitor, Cuff Module, Chest Sensor, Thumb Sensor, and Power Pack require cleaning and disinfection prior to reuse on a different patient. To prevent possible cross-contamination, properly clean and/or disinfect all ViSi Mobile reusable components between patients.



If the ViSi Power Pack beeper/buzzer sounds or the Red LED is permanently lit, the ViSi Power Pack should be disconnected from the patient immediately.



Do not clean the ViSi Mobile Monitor, Cuff Module, Chest Sensor, Thumb Sensor, or ViSi Power Pack with detergents while worn by the patient.



Do not clean the ViSi Mobile Monitor, the Cuff Module, or the Power Pack while it is plugged into the ViSi Mobile Charger.



Do not apply liquid to the ViSi Mobile Cuff Module or the Power Pack. To clean, use a damp cloth.



Ensure the sensor connector contacts are thoroughly dried to prevent possible malfunction.



Thumb sensors which are saturated with liquid should be allowed to air dry thoroughly before re-use.



Do not use bleach, abrasive cleaning agents or organic solvents on any of the ViSi Mobile Monitoring System components.



Use only recommended clenaing/disinfecting agents to prevent damage to the device and components. See page 107.



Do not autoclave the ViSi Mobile Monitor, its components, or accessories.



Do not use excessive amounts of liquid when cleaning the ViSi Mobile Chest Sensor or Thumb Sensor.

Cleaning and Disinfection

Prior to cleaning and disinfecting:

- 1. Pre-clean at the point of use to remove and prevent drying of soil and contaminants.
- 2. Ensure all components are disconnected, including the ViSi Mobile Monitor from the Wrist Cradle and the Thumb Sensor from the Thumb Wrap.
- 3. When cleaning the optional ViSi Power Pack, first remove the Power Pack from the Power Pack Cradle. All components of the ViSi Power Pack should be cleaned and disinfected between uses.

Recommended cleaning/disinfection agents. Use either of the following:

- 1. Clean with soap or detergent followed by disinfection with 70% isoprophyl alcohol.
- 2. Clean and disinfect with Super Sani-Cloth® Germicidal Disposable Wipes.

Cleaning and Disinfection

To clean the ViSi Mobile Monitoring System components

1. Hand-wash the System components using mild soap or detergent (e.g. Alconox) and water.

Do not appy liqiud to the Cuff Module or Power Pack, instead use a damp cloth.

- 2. A soft-bristled brush may be used for heavily soiled areas, as needed.
- 3. Dry thoroughly using a soft cloth or paper towel.
- 4. Visually examine the reusable components to ensure all soil contaminants have been removed.
- 5. Repeat the above cleaning process as required.

Note: Use a new Super Sani-Cloth®; disinfect according to manufacturer's recommended procedure.

To disinfect the ViSi Mobile Monitoring System components



Do not use bleach, abrasive cleaning agents or organic solvents on any of the ViSi Mobile Monitoring System components.



Do not autoclave the ViSi Mobile Monitor, its components, or accessories.



Do not use excessive amounts of liquid when cleaning the ViSi Mobile Chest Sensor CableChest Sensor or the ViSi Mobile Thumb Sensor.

To disinfect the ViSi Mobile Monitoring System components:

- 1. Disinfect the reusable components by wiping with a Super Sani-Cloth® (purple top) or use a basic wipe moistened with ≤70% isopropyl alcohol.
- 2. Dry thoroughly using a soft cloth or paper towel.

Note: Use a new Super Sani-Cloth®; disinfect according to manufacturer's recommended procedure.

8.4 Inspecting Equipment and Accessories

After cleaning and disinfecting, you should visually inspect the ViSi Mobile Monitoring System components and replace any System components that show evidence of anomalies.

- 1. For each component, examine the exteriors for cleanliness and general physical conditions. Ensure the housings are not cracked or broken, that everything is present, there are no spilled liquids and no signs of abuse.
- 2. Inspect all component cables for damage. Check their strain relief (at flex points) for general condition. Ensure there are no breaks or cracks in the cables. If any cables show signs of damage, do not use.
- 3. Inspect all disposable accessories (Wrist Cradle, Cuff, Thumb Strap, Securements, etc). If any show signs of damage or pre-use, do not use.

8.4.1 ViSi Mobile Chest Sensor

The Chest Sensor measures ECG/Respiration Rate (impedance pneumography) and skin surface temperature. A standard patient simulator can be used to verify operation against the specifications found in this Manual. The temperature sensor can be checked by submersing the sensor in a heated water bath until the temperature sensor is submerged and comparing the ViSi displayed temperature against a calibrated thermometer. Allow time for the ViSi temperature sensor to equilibrate with the water bath for the time specified in the Temperature Specifications in this Manual.

8.4.2 ViSi Mobile SpO₂ Sensor

The functionality of the SpO_2 sensor can be verified using standard patient simulators. However, accuracy should NOT be determined from patient simulators since they cannot duplicate human physiology. The only way to determine accuracy is to compare the ViSi reading against a blood gas value. When troubleshooting in a clinical setting, first inspect the sensor for proper placement as shown in this User Manual.

8.4.3 ViSi Mobile Cuff Module

The functionality of the Cuff Module can be verified using a patient simulator capable of simulating oscillometric blood pressure during the cuff inflation cycle. Consult your NIBP patient simulator manual for information.

8.4.4 ViSi Mobile Charger

The charger initiates an internal calibration each time it is powered. In the case of an internal failure, the indicator light will NOT turn green under any condition. If such a condition occurs return the Charger to Sotera for service.

8.4.5 ViSi Mobile Remote Viewer/Appliance

Refer to hardware manuals provided at installation for functional verification. Software checks are provided remotely by Sotera Wireless, Inc. over a secure remote access (similar to a VPN) connection installed at the time of installation.

Inspecting Equipment and Accessories

8.4.6 ViSi Mobile Monitoring System Battery Replacement

Within the ViSi Mobile Monitor, Cuff Module, and Power Pack, the battery is sealed. The battery technology is closely integrated with safety circuits and software to protect from hazardous and harmful conditions. The battery cannot be replaced with normal biomedical service tools. All battery service and replacement is performed by Sotera Wireless. Inc.

8.4.7 ViSi Mobile Optional Power Pack

Please see Appendix B -ViSi Power Pack on page 207

Product Disposal

8.5 Product Disposal



To avoid contaminating or infecting personnel, the environment or other equipment, make sure to disinfect and decontaminate the ViSi Mobile Monitoring System, Thumb Sensor and disposables components appropriately before disposing of them in accordance with your country's laws for equipment containing electrical and electronic parts.

The ViSi Mobile Monitoring System components are designated for separate collection at an appropriate collection point. Do not dispose of as household waste. Refer to your facility's procedures.



After patient use, the disposables from the ViSi Disposable Kit may contain bio-hazard materials. Handle and dispose of these items according to your facility's policies.



Disposables from the ViSi Disposable Kit should be disposed of per your facility's procedures for bio-hazard materials.

Contact the Sotera Wireless, Inc. Customer Service Department or the Sotera Wireless, Inc. representative in your area to obtain additional information about cleaning and disinfecting the ViSi Mobile Monitoring System components or product disposal.

Product Disposal



Appendix A - Warranty

Warranty

Sotera Wireless, Inc. warrants to End User, for a period of one (1) year from the date of delivery, unless otherwise noted in specific documentation, that the products sold by Sotera Wireless, Inc. will operate in accordance with Sotera Wireless, Inc.'s published documentation in effect on the date of delivery or Sotera Wireless, Inc. will, at its sole discretion and expense, repair or replace the products. Replacements will be warranted for the remainder of the warranty period in effect on the original product purchased, unless otherwise mandated by applicable law. Products include Sotera Wireless, Inc. equipment only but does not include disposables / consumables. Sotera Wireless, Inc. warrants that its disposables / consumables products will be free from defects in workmanship and materials for a period of one (1) year from the date of purchase or the expiration date whichever occurs first.

Third Party Branded Products

Sotera Wireless, Inc. will not be deemed to provide, nor be responsible for, warranty, related remedy or support with respect to hardware, software or services purchased from a third party unless such party is a Sotera Wireless, Inc. authorized partner services Sotera Products and Services, unless otherwise agreed in writing between the parties.

Typically, in case of a defective 3rd party item under warranty, Sotera Wireless, Inc. will make arrangements with the 3rd party manufacturer to issue a replacement. The replacement will be sent directly to the End User site from the 3rd party manufacturer. No Return Material Authorization (RMA) will be issued by Sotera Wireless, Inc., instead a Sotera Case Number will be issued for the reported issue. The End User is responsible for complying with the manufacturer's replacement procedures.

Warranty Exclusions

Sotera Wireless, Inc. will not be liable under this warranty if its testing and/or examination discloses that the alleged defect in the Sotera Wireless, Inc. equipment does not exist or was caused by end user's or any unauthorized third person's misuse, neglect, improper installation or testing, attempts to repair, or any other cause beyond the scope of the intended use, or by accident, fire, lightning or other hazard or event of force majeure. The warranty for any hardware will become void if a hardware component is installed as an add-on and/or replacement part on the original hardware and such component part has not been approved for such inclusion by Sotera Wireless, Inc. The warranty for software will be voided if the software is modified, except as authorized in writing by Sotera Wireless, Inc.

Sotera Wireless, Inc. Responsibility

In no event shall Sotera Wireless, Inc. be liable to end user or any third parties for any consequential, incidental, indirect, exemplary, punitive, contingent, statutory or any other special damages. Sotera Wireless, Inc.'s liability for damages on account of a claimed defect in any product delivered by Sotera Wireless, Inc. shall in no event exceed the purchase price of the product on which the claim is based. Specifically, and without limiting the generality of the foregoing, Sotera Wireless, Inc. shall not be responsible or liable to end user or any third party for any lost profits, or any consequential, incidental, punitive, contingent, statutory or any other special damages for any breach of warranty or other breach of Sotera Wireless, Inc.'s obligations under this agreement. Sotera Wireless, Inc. shall not be liable for damages relating to any instrument, equipment, or apparatus with which the product sold under this agreement is used. In addition, Sotera Wireless, Inc. disclaims all liability of any kind of Sotera Wireless, Inc.'s suppliers.

The foregoing warranties and remedies are exclusive and are in lieu of all other warranties, express or implied, either in fact or by operation of law, statutory or otherwise including warranties of merchantability and fitness for a particular purpose or non infringement.

Sotera Wireless, Inc. does not assume or authorize any other person to assume for it any other or greater liability in connection with the sale, installation, servicing, maintenance or use of Sotera Wireless, Inc. hardware, and Sotera Wireless, Inc. makes no warranty whatsoever with respect to any third-party branded products supplied by it hereunder.

Sotera Wireless, Inc. Responsibility

Sotera Wireless, Inc. is responsible for the effects on safety, reliability and performance of the equipment only if:

- 1. Assembly operations, extensions, readjustments, modifications or repairs are carried out by persons authorized by Sotera Wireless, Inc. and
- 2. The equipment is used in accordance with the instructions for use.

Contact Sotera Wireless

Toll-Free: +1-866-232-6126

International: +1-858-427-4620

Fax: +1-858-999-2487

E-mail: support@soterawireless.com

EXHIBIT 3

Complaint

Case 1:22-cv-01378-MN-JLH Document 175-1 Filed 07/14/23 Page 140 of 561 PageID #:

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Plaintiff Masimo Corporation ("Masimo") hereby complains Defendants Sotera Wireless, Inc. ("Sotera") and Hon Hai Precision Industry Co. Ltd. ("Foxconn") and alleges as follows:

I. THE PARTIES

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1. Plaintiff Masimo is a Delaware corporation having its principal place of business at 52 Discovery, Irvine, California 92618.

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products intended to compete with Masimo's products.

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2. Defendant Sotera is a California corporation having a principal place of business at 10020 Huennekens Street, San Diego, CA 92121. Sotera markets the ViSi Mobile Monitoring System, a monitoring platform and set of

3. Defendant Foxconn also known as Foxconn Technology Group, is a corporation organized and existing under the laws of Taiwan, with its principal place of business at No. 66, Zhongshan Road, Tucheng Industrial Zone, Tucheng Dist., New Taipei City, Taiwan, R.O.C. Foxconn is a multinational electronics manufacturing company. Foxconn owns an undisclosed stake in Sotera, and on information and belief, Foxconn controls Sotera and Sotera's management team.

II. JURISDICTION AND VENUE

- This is a civil action for patent infringement arising under the 4. patent laws of the United States, 35 U.S.C. §§ 100, et seq., more particularly, 35 U.S.C. §§ 271 and 281.
- This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).
- 6. Sotera resides in California and is subject to personal jurisdiction in California, and, on information and belief, has committed the acts complained of in this Judicial District.
- 7. Foxconn resides in Taiwan and is subject to specific and general personal jurisdiction in California due to Foxconn's substantial business in

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- California. For example, Foxconn maintains a branch office at 105 S. Puente Street, Brea, California 92821. Furthermore, Foxconn has filed suit in this judicial district. On information and belief, Foxconn has transacted business in this judicial district and committed acts within this judicial district giving rise to this action, directly and/or through subsidiaries, agents and partners.
- 8. Venue is proper in this Judicial District pursuant to 28 U.S.C. § 1400(b) as to Sotera because Sotera has its regular and established place of business in the County of San Diego within the Southern District of California.
- 9. Venue is proper in this Judicial District pursuant to 28 U.S.C. § 1391(c)(3) as to Foxconn.

III. MASIMO'S INNOVATIVE TECHNOLOGY

10. Masimo is a medical technology company that revolutionized pulse oximetry and is the only company to have succeeded in developing noninvasive patient monitoring technologies for hemoglobin, methemoglobin, carboxyhemoglobin. Pulse oximetry is a noninvasive method for monitoring a person's arterial oxygen saturation (also called "SpO2") and pulse rate from a sensor that is attached to a user. Before Masimo, pulse oximetry was plagued by unreliability, often when the measurement was needed most, due to patient motion and low peripheral blood flow (known as "low perfusion"). The industry had essentially given up on solving this problem, concluding it was largely unsolvable. Clinicians had to live with the results – patient monitors gave excessive false alarms, froze their measurements for prolonged periods of time despite potential changes in oxygen saturation or pulse rate, delayed notification of alarms due to long averaging times of sensor data, produced inaccurate measurements, or were unable to obtain data on the most critical patients and babies who cannot be instructed to stay still. Masimo's pioneering technology, known as Masimo Signal Extraction Technology ("Masimo SET"), solved this problem and dramatically improved patient safety by accurately

monitoring and reporting oxygen saturation and pulse rate even during motion and low perfusion.

- 11. Following its success in pulse oximetry, Masimo subsequently invested in developing additional breakthrough measurement technologies, such as non-invasively measuring total hemoglobin, methemoglobin, and carboxyhemoglobin. Masimo has continued to innovate, succeeding where others have consistently failed. Masimo was the first, and remains the only, company delivering these game-changing technologies to hospitals in the United States.
- 12. With measurement innovation at its core, Masimo helped clinicians benefit from continuous monitoring of key physiologic measurements and intuitive centralized displays of real-time patient data. Masimo applied the power of its breakthrough measurements to patient-worn monitors designed to allow patient mobility and continuous monitoring. Masimo's small wearable monitors allow untether monitoring that promote greater patient comfort and independence. Masimo also developed monitors with wireless communications technologies to further advance continuous monitoring. These advances also reduce the need for nurses to disconnect a monitor each time a patient gets out of bed.
- 13. To benefit clinicians and patients in comprehending Masimo's gold-standard data, Masimo developed intuitive displays of real-time patient data. Masimo's contributions include specific techniques for presenting large amounts of data in a quickly comprehensible manner. Using color, animation, arrangement, and organization, Masimo's technologies allow clinicians to rapidly assess patient status. When paired with the reduction in false alarms and overall accuracy of Masimo's technologies, these visual interfaces allow for efficient monitoring of patient status and improve patient care.

- 14. Masimo's technologies also include Masimo's pioneering Patient SafetyNet System ("Masimo Patient SafetyNet"), which improves patient safety by providing remote monitoring and clinician notification of patient data such as continuous pulse oximetry, heart rate, blood pressure, electrocardiogram, and ventilation monitoring. Masimo Patient SafetyNet combines the gold-standard performance of Masimo's monitoring technologies with information collected from any connected Masimo or third-party patient device to provide alarms, alerts and near-real time information to be sent to remote locations, for example, directly to clinicians. The system allows clinicians to monitor multiple patients simultaneously and to automatically transfer data from medical devices to electronic medical records. Masimo's innovation in that space continue to drive medical monitoring technologies and improve patient outcomes.
 - 15. From its inception, Masimo has continuously developed cutting-edge, noninvasive patient monitoring technologies. Masimo sought and received numerous U.S. patents for many of its inventions in these areas. Masimo's revolutionary technology was a key to its gaining significant market praise and penetration. After introduction into the market, many competitors, much larger than Masimo, used Masimo's technology without a license, resulting in patent infringement lawsuits that resulted in jury verdicts of infringement, damages, and confirmation of the validity of Masimo's innovations.

IV. THE PATENTS-IN-SUIT

16. Masimo is the owner by assignment of U.S. Patent No. 9,788,735 entitled "Body Worn Mobile Medical Patient Monitor" ("the '735 patent"), which the United States Patent and Trademark Office lawfully and duly issued on October 17, 2017. A true and correct copy of the '735 patent is attached hereto as Exhibit 1.

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- 17. Masimo is the owner by assignment of U.S. Patent No. 9,795,300 entitled "Wearable Portable Patient Monitor" ("the '300 patent"), which the United States Patent and Trademark Office lawfully and duly issued on October 24, 2017. A true and correct copy of the '300 patent is attached hereto as Exhibit 2.
- 18. Masimo is the owner by assignment of U.S. Patent No. 9,872,623 entitled "Arm Mountable Portable Patient Monitor" ("the '623 patent"), which the United States Patent and Trademark Office lawfully and duly issued on January 23, 2018. A true and correct copy of the '623 patent is attached hereto as Exhibit 3.
- 19. Masimo is the owner by assignment of U.S. Reissue Patent No. RE47,218 entitled "Adaptive Alarm System" ("the RE218 patent"), which the United States Patent and Trademark Office lawfully and duly issued on February 5, 2019. A true and correct copy of the RE218 patent is attached hereto as Exhibit 4.
- 20. Masimo is the owner by assignment of U.S. Reissue Patent No. RE47,244 entitled "Alarm Suspend System" ("the RE244 patent"), which the United States Patent and Trademark Office lawfully and duly issued on February 19, 2019. A true and correct copy of the RE244 patent is attached hereto as Exhibit 5.
- 21. Masimo is the owner by assignment of U.S. Reissue Patent No. RE47,249 entitled "Alarm Suspend System" ("the RE249 patent"), which the United States Patent and Trademark Office lawfully and duly issued on February 19, 2019. A true and correct copy of the RE249 patent is attached hereto as Exhibit 6.
- 22. Masimo is the owner by assignment of U.S. Patent No. 10,213,108 entitled "Arm Mountable Portable Patient Monitor" ("the '108 patent"), which the United States Patent and Trademark Office lawfully and duly issued on

February 26, 2019. A true and correct copy of the '108 patent is attached hereto as Exhibit 7.

- 23. Masimo is the owner by assignment of U.S. Patent No. 10,255,994 entitled "Physiological Parameter Alarm Delay" ("the '994 patent"), which the United States Patent and Trademark Office lawfully and duly issued on April 9, 2019. A true and correct copy of the '994 patent is attached hereto as Exhibit 8.
- 24. Masimo is the owner by assignment of U.S. Reissue Patent No. RE47353 entitled "Alarm Suspend System" ("the RE47353 patent"), which the United States Patent and Trademark Office lawfully and duly issued on April 16, 2019. A true and correct copy of the RE353 patent is attached hereto as Exhibit 9.

V. <u>DEFENDANTS' ACTIVITIES</u>

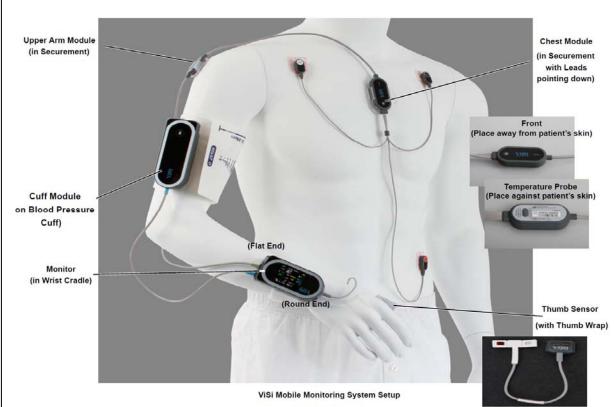
25. Sotera has made, used, offered to sell, and/or sold within the United States, and/or has imported into the United States, products including at least Sotera's ViSi Mobile Monitoring System, a platform for vital signs monitoring, including pulse oximetry, pulse rate, and respiration rate. The ViSi Mobile Monitoring System includes a ViSi Mobile Monitor, ViSi Mobile Thumb Sensor, ViSi Mobile Cuff Module, ViSi Mobile Chest Sensor Cable, ViSi Mobile Wrist Strap, and ViSi Mobile Wrist Cradle. A picture of the ViSi Mobile Monitoring System from the product's User Manual is reproduced below:

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26. On information and belief, Foxconn has directly or indirectly controlled activities by Sotera including making, using, offering to sell, and/or selling within the United States, and/or importing into the United States, products including at least Sotera's ViSi Mobile Monitoring System. Foxconn has announced plans to make Sotera's ViSi Mobile Monitoring components and products, including at least batteries and sensors for the products.

VI. CLAIMS FOR PATENT INFRINGEMENT VII. FIRST CLAIM FOR RELIEF (Infringement of U.S. Patent No. 9.788.735)

(Infringement of U.S. Patent No. 9,788,735)

- 27. Masimo realleges and reincorporates the allegations set forth in paragraphs 1 through 26.
- 28. Upon information and belief, Sotera products, including at least the ViSi Mobile Monitoring System products, infringe at least Claim 20 of the '735 patent under at least 35 U.S.C. § 271(a), (b), and (c).

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- 29. Upon information and belief, Sotera has directly infringed one or more claims of the '735 patent through manufacture use, sale, offer for sale, and/or importation into the United States of medical monitoring devices, including the ViSi Mobile Monitoring System.
- 30. Upon information and belief, Foxconn has directly infringed or induced Sotera and/or Sotera's customers to infringe one or more claims of the '735 patent. For example, on information and belief Foxconn has directed Sotera to manufacture use, sell, offer for sale, and/or import into the United States, electronic patient monitoring systems, including the ViSi Mobile Monitoring System.
- 31. For example, the ViSi Mobile Monitor of the ViSi Mobile Monitoring System includes all of the limitations of Claim 20 of the '735 patent. The ViSi Mobile is a body worn portable patient monitoring device configured to provide on-patient and remote monitoring of patient physiological parameters, the portable patient monitoring device. The ViSi Mobile includes a pulse oximetry sensor configured to be wrapped around a digit of a patient, the patient's thumb. The ViSi Mobile pulse oximetry sensor includes a light emitter configured to emit light into a tissue site of the patient's thumb. The ViSi Mobile pulse oximetry sensor also includes a light detector configured output a first signal. That first signal is responsive to at least a portion of the emitted light after attenuation by tissue on the patient's thumb. ViSi Mobile pulse oximetry sensor also includes a cable extending from the pulse oximetry sensor and configured to electrically convey the first signal. The ViSi Mobile further includes a blood pressure sensor configured to output a second signal responsive to at least a blood pressure parameter of the patient. The ViSi Mobile also includes an additional sensor arrangement, the ViSi Mobile chest sensor, configured to output a third signal responsive to an additional physiological parameter of the patient, temperature or respiration rate. The ViSi Mobile also

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has a housing configured to be secured to a lower arm of the patient, the housing having a size and shape configured to be secured to the lower arm of the patient. The ViSi Mobile also has a strap mountable to the back side of the housing, the strap configured to secure the housing to the lower arm of the patient. The ViSi Mobile includes a display positioned on a front side of the housing that is opposite a back side of the housing. The ViSi Mobile display is configured to show the status of the ViSi Mobile and multiple parameter measurements, such as SpO₂ and blood pressure, so as to be viewable by a user. The ViSi Mobile display is positioned centrally on the front side of the ViSi Mobile and is sized such that the display spans most of a length of a shortest dimension of the front side of the housing. The front side of the ViSi Mobile housing comprises a single user interface and a bezel. The ViSi Mobile also includes one or more user input mechanisms, such as the touch screen of the device, configured to control an operational mode of the ViSi Mobile in response to inputs from a user. The ViSi Mobile also includes a first sensor port positioned on a face of a first side of the housing. The face of the first side of the housing of the ViSi Mobile is configured to face toward a hand having the digit of the patient under measurement when the housing is secured to the lower arm of the patient. The first sensor port of the ViSi Mobile is configured to removably physically couple with the ViSi Mobile thumb pulse oximetry sensor via the cable and to electrically receive the first signal from the pulse oximetry sensor. The cable of the thumb sensor of the ViSi Mobile is configured to run from the first sensor port, at least part way along a path substantially perpendicular to the face of the first side of the housing, down the arm of the patient, and to the digit of the patient, the thumb, to which the pulse oximetry sensor is configured to be wrapped around. The front side of the housing of the ViSi Mobile is raised from the strap and the lower arm of the patient to enable positioning of the first sensor port on the first side of the housing between the lower arm of the patient and the

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front side of the housing. The top of the first sensor port of the ViSi Mobile is located below the front of the housing. The ViSi Mobile also includes a second sensor port positioned on the housing and configured to provide wired electrical communication with the ViSi Mobile blood pressure sensor arrangement. The ViSi Mobile second sensor port electrically receives a second signal from the blood pressure sensor arrangement. The ViSi Mobile also includes a third sensor port positioned on the housing and configured to provide electrical wired communication with the ViSi Mobile ECG sensor arrangement and electrically receives the third signal from the additional sensor arrangement. The ViSi Mobile also includes a rechargeable battery positioned within the housing and configured to power the portable patient monitoring device such that the portable patient monitoring device is portable and wearable by the patient. The ViSi Mobile further includes one or more signal processing arrangements positioned within the housing. The ViSi Mobile signal processors receive the first signal from the pulse oximetry sensor via one or more sensor interfaces, that first signal is provided at least partly as an analog signal. The ViSi Mobile signal processor process the first signal from the pulse oximetry sensor to determine measurements of oxygen saturation and pulse rate. The signal processor also receives the second signal from the blood pressure sensor arrangement via the one or more sensor interfaces, the second signal responsive to at least a blood pressure parameter of the patient. The ViSi mobile signal processor also receives the third signal from the additional sensor arrangement via the one or more sensor interfaces, the third signal responsive to the at least temperature or respiration rate of the patient. That third signal is provided at least partly as a digital signal. The ViSi Mobile also causes the measurements of oxygen saturation, pulse rate, blood pressure, and the at least one additional physiological parameter, temperature or ECG from the chest sensor, to all be displayed on the ViSi Mobile display. and a The ViSi Mobile includes an

- 802.11b transmitter positioned within the housing and configured to: wirelessly transmit a transmit signal including the information indicating the measurements of oxygen saturation, pulse rate, blood pressure, and the temperature or respiration rate to a separate computing device, such as the ViSi Remote Viewer. The ViSi Remote viewer is configured to display, on its remote display, the measurements of oxygen saturation, pulse rate, blood pressure, and temperature or respiration rate.
- 32. Upon information and belief, Sotera and Foxconn have monitored Masimo's patents, including the '735 patent by hiring former Masimo employees and after previous trade secret misappropriation litigation asserted against Sotera by Masimo. Upon further information and belief, through the knowledge of the '735 patent gained by monitoring Masimo's patents, Sotera and Foxconn knew or should have known that these activities would cause direct infringement. Sotera and Foxconn also had knowledge of the '735 patent no later than the filing of this Complaint.
- 33. Upon information and belief, Sotera and Foxconn actively induce others to infringe the '735 patent by marketing and selling the above ViSi Mobile Monitoring Systems, knowing and intending that such systems would be used by customers and end users in a manner that infringes the '735 patent. To that end, Sotera provides instructions and teachings to customers and end users that such ViSi Mobile Monitoring Systems be used to infringe the '735 patent. Sotera's acts and Foxconn's acts constitute infringement of the '735 patent in violation of 35 U.S.C. § 271(b).
- 34. Upon information and belief, Sotera and Foxconn actively induce health-care service providers and users to directly infringe the asserted claims of the '735 patent. By way of example only, upon information and belief, Sotera and Foxconn actively induce direct infringement of the '735 patent by providing directions, demonstrations, guides, manuals, training for use, and/or other

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materials necessary for the use, refurbishing, and/or servicing of the ViSi Mobile Monitor. Upon information and belief, Sotera and Foxconn knew or should have known that these activities would cause direct infringement.

- Upon information and belief, Sotera's acts and Foxconn's acts 35. constitute contributory infringement of the '735 patent in violation of 35 U.S.C. § 271(c). Upon information and belief, Sotera and Foxconn contributorily infringe because, among other things, Sotera offers to sell and/or sells within the United States, and/or imports into the United States, components of the ViSi Mobile Monitoring System that constitute material parts of the invention of the asserted claims of the '735 patent, are not staple articles or commodities of commerce suitable for substantial non-infringing use, and are known by Sotera and Foxconn to be especially made or especially adapted for use in an infringement of the '735 patent.
- Upon information and belief, Sotera's infringement of the '735 patent has been, and continues to be, willful, deliberate, and intentional by continuing its acts of infringement after becoming aware of the '735 patent and its infringement thereof, thus acting in reckless disregard of Masimo's patent rights.
- 37. As a consequence of Sotera's and Foxconn's infringement of the '735 patent, Masimo has suffered and will continue to suffer irreparable harm and injury, including monetary damages in an amount to be determined at trial.
- Upon information and belief, unless enjoined, Sotera, Foxconn, 38. and/or others acting on behalf of Sotera, will continue their infringing acts, thereby causing additional irreparable injury to Masimo for which there is no adequate remedy at law.

VIII. SECOND CLAIM FOR RELIEF

(Infringement of U.S. Patent No. 9,795,300)

39. Masimo realleges and reincorporates the allegations set forth in paragraphs 1 through 38.

40. Upon information and belief, Sotera products, including at least the ViSi Mobile Monitoring System products, infringe at least Claims 16-20 of the '300 patent under at least 35 U.S.C. § 271(a), (b), and (c).

41. Upon information and belief, Sotera has directly infringed one or more claims of the '300 patent through manufacture use, sale, offer for sale, and/or importation into the United States of medical monitoring devices, including the ViSi Mobile Monitoring System.

42. Upon information and belief, Foxconn has directly infringed or induced Sotera and/or Sotera's customers to infringe one or more claims of the '300 patent. For example, on information and belief Foxconn has directed Sotera to manufacture use, sell, offer for sale, and/or import into the United States, electronic patient monitoring systems, including the ViSi Mobile Monitoring System.

43. For example, the ViSi Mobile Monitor of the ViSi Mobile Monitoring System includes all of the limitations of Claim 16 of the '300 patent. The ViSi Mobile is a battery-powered wearable physiological monitoring device configured to communicate with multiple types of sensor arrangements via a plurality of sensor interfaces. The ViSi Mobile has three sensor communication ports including: a first sensor communication port configured to provide wired communication with a first type of physiological sensor arrangement, a ViSi Mobile thumb pulse oximetry sensor. The first sensor port of the ViSi Mobile is positioned on the device such that a wire extending from the first sensor communication port to the first type of physiological sensor arrangement

extends from the device along an axis perpendicular to a face of the device upon

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which the first sensor port is positioned. The ViSi Mobile also includes a second sensor communication port configured to provide wired communication with a second type of physiological sensor arrangement, a ViSi Mobile blood pressure sensor. The blood pressure sensor is different from pulse oximetry The ViSi Mobile also includes a third sensor communication port sensor. configured to provide wired communication with a third type of physiological sensor arrangement, an ECG. The ECG different from both the pulse oximetry and blood pressure sensor arrangements. The ViSi Mobile includes a plurality of sensor interfaces including a first sensor interface configured to receive a first signal from a pulse oximetry sensor. The first signal includes analog information. The ViSi Mobile includes a second sensor interface configured to receive a second signal from a blood pressure sensor, the second signal including digital information. The ViSi Mobile further includes a third sensor interface, the ECG interface, configured to receive a third signal from an ECG sensor arrangement. The plurality of sensor interfaces in the ViSi Mobile are configured to output one or more signals indicative of physiological parameters sensed by the first, second, and third sensor arrangements. The ViSi Mobile further includes a display positioned on its face configured to display information while the wearable physiological monitoring device is being worn The ViSi Mobile also includes a processor configured to be by a patient. responsive to the one or more signals indicative of the physiological parameters, and cause to be displayed, on the display, physiological parameter measurements. The ViSi Mobile combines information indicative of the one or more signals into a single digital word or bit stream for transmission over The ViSi Mobile encodes the single digital word or bit stream to generate a baseband signal for 802.11b. The ViSi Mobile also includes a transmitter configured to: modulate the baseband signal with a carrier to generate a transmit signal. In operation, the ViSi Mobile wirelessly transmits

the transmit signal to a receiving patient monitoring device that is not wired to the wearable physiological monitoring device. The ViSi Mobile also includes a single cell Li-ION battery configured to provide power to at least the processor, the display, the transmitter, and the first sensor arrangement via the first sensor communication port such that the wearable physiological monitoring device is portable and wearable by a patient.

- 44. Upon information and belief, Sotera and Foxconn have monitored Masimo's patents, including the '300 patent by hiring former Masimo employees and following previous trade secret misappropriation litigation asserted against Sotera by Masimo. Upon further information and belief, through the knowledge of the '300 patent gained by monitoring Masimo's patents, Sotera and Foxconn knew or should have known that these activities would cause direct infringement. Sotera and Foxconn also had knowledge of the '300 patent no later than the filing of this Complaint.
- 45. Upon information and belief, Sotera and Foxconn actively induce others to infringe the '300 patent by marketing and selling the above ViSi Mobile Monitoring Systems, knowing and intending that such systems would be used by customers and end users in a manner that infringes the '300 patent. To that end, Sotera provides instructions and teachings to its customers and end users that such ViSi Mobile Monitoring Systems be used to infringe the '300 patent. Sotera's acts and Foxconn's acts constitute infringement of the '300 patent in violation of 35 U.S.C. § 271(b).
- 46. Upon information and belief, Sotera and Foxconn actively induce health-care service providers and users to directly infringe the asserted claims of the '300 patent. By way of example only, upon information and belief, Sotera and Foxconn actively induce direct infringement of the '300 patent by providing directions, demonstrations, guides, manuals, training for use, and/or other materials necessary for the use, refurbishing, and/or servicing of the ViSi

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Mobile Monitor. Upon information and belief, Sotera and Foxconn knew or should have known that these activities would cause direct infringement.

- 47. Upon information and belief, Sotera's acts and Foxconn's acts constitute contributory infringement of the '300 patent in violation of 35 U.S.C. § 271(c). Upon information and belief, Sotera and Foxconn contributorily infringe because, among other things, Sotera offers to sell and/or sells within the United States, and/or imports into the United States, components of the ViSi Mobile Monitoring System that constitute material parts of the invention of the asserted claims of the '300 patent, are not staple articles or commodities of commerce suitable for substantial non-infringing use, and are known by Sotera and Foxconn to be especially made or especially adapted for use in an infringement of the '300 patent.
- 48. Upon information and belief, Sotera's and Foxconn's infringement of the '300 patent has been, and continues to be, willful, deliberate, and intentional by continuing its acts of infringement after becoming aware of the '300 patent and its infringement thereof, thus acting in reckless disregard of Masimo's patent rights.
- 49. As a consequence of Sotera's and Foxconn's infringement of the '300 patent, Masimo has suffered and will continue to suffer irreparable harm and injury, including monetary damages in an amount to be determined at trial.
- 50. Upon information and belief, unless enjoined, Sotera, Foxconn, and/or others acting on behalf of Sotera, will continue their infringing acts, thereby causing additional irreparable injury to Masimo for which there is no adequate remedy at law.

THIRD CLAIM FOR RELIEF

(Infringement of U.S. Patent No. 9,872,623)

51. Masimo realleges and reincorporates the allegations set forth in paragraphs 1 through 50.

- 52. Upon information and belief, Sotera products, including at least the ViSi Mobile Monitoring System products, infringe at least Claims 1-16 of the '623 patent under at least 35 U.S.C. § 271(a), (b), and (c).
- 53. Upon information and belief, Sotera has directly infringed one or more claims of the '623 patent through manufacture use, sale, offer for sale, and/or importation into the United States of medical monitoring devices, including the ViSi Mobile Monitoring System.
- 54. Upon information and belief, Foxconn has directly infringed or induced Sotera and/or Sotera's customers to infringe one or more claims of the '623 patent. For example, on information and belief Foxconn has directed Sotera to manufacture use, sell, offer for sale, and/or import into the United States, electronic patient monitoring systems, including the ViSi Mobile Monitoring System.
- 55. For example, the ViSi Mobile Monitor of the ViSi Mobile Monitoring System includes all of the limitations of Claim 1 of the '623 patent. The ViSi Mobile Monitor is an arm mountable portable patient monitoring device configured for both on-patient monitoring of parameter measurements using one or more sensors operatively connected to the portable patient monitoring device and wireless transmission of parameter measurements. The ViSi Mobile Monitor includes a pulse oximetry sensor at its thumb sensor configured to be wrapped around a digit of a patient. The pulse oximetry sensor of the ViSi Mobile Monitor includes a light emitter configured to emit light into a tissue site of the digit of the patient; a light detector configured output a signal responsive to at least a portion of the emitted light after attenuation by tissue of the tissue site; and a tail configured to electrically convey the signal. The ViSi Mobile Monitor includes a housing configured for, and having a size and shape configured for, mounting to a lower arm of the patient. The ViSi Mobile Monitor includes a display positioned on a front side of the housing that is

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opposite a back side of the housing. The display of the ViSi Mobile Monitor is configured to show a status of the portable patient monitoring device and one or more parameter measurements so as to be viewable by a user. The ViSi Mobile Monitor includes a first sensor port positioned on a first side of the housing and the first side of the housing is configured to face toward a hand having the digit of the patient under measurement. The first sensor port of the ViSi Mobile Monitor is configured to physically couple to the tail of the pulse oximetry sensor and to electrically receive the signal from the pulse oximetry sensor. The first sensor port of the ViSi Mobile Monitor is positioned on the first side of the housing such that, when the tail is physically coupled to the first sensor port, the tail extends from the first sensor port along an axis perpendicular to a face of the first side of the housing on which the first sensor port is positioned. The ViSi Mobile Monitor also includes a second sensor port configured to receive information from an EKG sensor arrangement via a wired connection and a third sensor port configured to receive information from a blood pressure sensor arrangement via a wired connection. The ViSi Mobile Monitor includes a Li-Ion rechargeable battery configured to power the ViSi Mobile Monitor including the pulse oximetry sensor. The ViSi Mobile Monitor includes one or more signal processing arrangements configured to receive the signal from the pulse oximetry sensor; derive, based on the signal, measurements of oxygen saturation and pulse rate; and cause to be displayed, on the display, the measurements of The ViSi Mobile Monitor includes a oxygen saturation and pulse rate. transmitter configured to wirelessly transmit a transmit signal indicative of the measurements of oxygen saturation and pulse rate to a separate computing device configured to display the measurements of oxygen saturation and pulse rate. The ViSi Mobile Monitor includes a wrist strap mountable to the back side of the housing. The wrist strap of the ViSi Mobile Monitor is configured to secure the housing to the lower arm of the patient.

- 56. Upon information and belief, Sotera and Foxconn have monitored Masimo's patents, including the '623 patent by hiring former Masimo employees and following previous trade secret misappropriation litigation asserted against Sotera by Masimo. Upon further information and belief, through the knowledge of the '623 patent gained by monitoring Masimo's patents, Sotera and Foxconn knew or should have known that these activities would cause direct infringement. Sotera and Foxconn also had knowledge of the '623 patent no later than the filing of this Complaint.
- 57. Upon information and belief, Sotera and Foxconn have actively induced others to infringe the '623 patent by marketing and selling the above ViSi Mobile Monitoring Systems, knowing and intending that such systems would be used by customers and end users in a manner that infringes the '623 patent. To that end, Sotera provides instructions and teachings to its customers and end users that such ViSi Mobile Monitoring Systems be used to infringe the '623 patent. Sotera's acts and Foxconn's acts constitute infringement of the '623 patent in violation of 35 U.S.C. § 271(b).
- 58. Upon information and belief, Sotera and Foxconn actively induce health-care service providers and users to directly infringe the asserted claims of the '623 patent. By way of example only, upon information and belief, Sotera actively induces direct infringement of the '623 patent by providing directions, demonstrations, guides, manuals, training for use, and/or other materials necessary for the use, refurbishing, and/or servicing of the ViSi Mobile Monitor. Upon information and belief, Sotera knew or should have known that these activities would cause direct infringement.
- 59. Upon information and belief, Sotera's acts and Foxconn's acts constitute contributory infringement of the '623 patent in violation of 35 U.S.C. § 271(c). Upon information and belief, Sotera and Foxconn contributorily infringe because, among other things, Sotera offers to sell and/or sells within the

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United States, and/or imports into the United States, components of the ViSi Mobile Monitoring System that constitute material parts of the invention of the asserted claims of the '623 patent, are not staple articles or commodities of commerce suitable for substantial non-infringing use, and are known by Sotera and Foxconn to be especially made or especially adapted for use in an infringement of the '623 patent.

- Upon information and belief, Sotera's and Foxconn's infringement of the '623 patent has been, and continues to be, willful, deliberate, and intentional by continuing its acts of infringement after becoming aware of the '623 patent and its infringement thereof, thus acting in reckless disregard of Masimo's patent rights.
- 61. As a consequence of Sotera's and Foxconn's infringement of the '623 patent, Masimo has suffered and will continue to suffer irreparable harm and injury, including monetary damages in an amount to be determined at trial.
- Upon information and belief, unless enjoined, Sotera, Foxconn, and/or others acting on behalf of Sotera, will continue their infringing acts, thereby causing additional irreparable injury to Masimo for which there is no adequate remedy at law.

FOURTH CLAIM FOR RELIEF

(Infringement of U.S. Reissue Patent No. RE47,218)

- 63. Masimo realleges and reincorporates the allegations set forth in paragraphs 1 through 62.
- 64. Upon information and belief, Sotera products, including at least the ViSi Mobile Monitoring System products, infringe at least Claims 1-10, and 12-18 of the RE218 patent under at least 35 U.S.C. § 271(a), (b), and (c).
- 65. Upon information and belief, Sotera has directly infringed one or more claims of the RE218 patent through manufacture use, sale, offer for sale,

and/or importation into the United States of medical monitoring devices, including the ViSi Mobile Monitoring System.

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- 66. Upon information and belief, Foxconn has directly infringed or induced Sotera and/or Sotera's customers to infringe one or more claims of the RE218 patent. For example, on information and belief Foxconn has directed Sotera to manufacture use, sell, offer for sale, and/or import into the United States, electronic patient monitoring systems, including the ViSi Mobile Monitoring System.
- 67. For example, the ViSi Mobile Monitor of the ViSi Mobile Monitoring System includes all of the limitations of Claim 1 of the RE218 patent. The ViSi Mobile Monitoring System is a system for reducing electronic alarms in a medical patient monitoring system. The ViSi Mobile Monitoring System includes a ViSi Mobile Monitor having an optical sensor at its thumb sensor configured to transmit optical radiation into a tissue site of a patient and detect attenuated optical radiation indicative of at least one physiological The ViSi Mobile Monitor includes one or more parameter of a patient. hardware processors in electronic communication with the optical sensor. The one or more hardware processors of the ViSi Mobile Monitor is configured to determine oxygen saturation values of the patient over a first period of time and, when at least one oxygen saturation value obtained over the first period of time exceeds a first alarm threshold, determine whether a first alarm should be triggered. The one or more hardware processors of the ViSi Mobile Monitor is configured to access a second alarm threshold to be applied during a second period of time subsequent to the first period of time. The second alarm threshold replaces the first alarm threshold, and the second alarm threshold has a value less than the at least one oxygen saturation value and greater than a lower limit and at an offset from the at least one oxygen saturation value. The offset is diminished as a difference between the at least first oxygen saturation value and

the lower limit diminishes. The one or more hardware processors of the ViSi Mobile Monitor is also configured to determine oxygen saturation values of the patient over the second period of time and trigger a second alarm based on at least one value of the oxygen saturation values obtained over the second period of time exceeding the second alarm threshold.

- 68. Upon information and belief, Sotera and Foxconn have monitored Masimo's patents, including the RE218 patent by hiring former Masimo employees and after previous trade secret misappropriation litigation asserted against Sotera by Masimo. Upon further information and belief, through the knowledge of the RE218 patent gained by monitoring Masimo's patents, Sotera and Foxconn knew or should have known that these activities would cause direct infringement. Sotera and Foxconn also had knowledge of the RE218 patent no later than the filing of this Complaint.
- 69. Upon information and belief, Sotera and Foxconn have actively induced others to infringe the RE218 patent by marketing and selling the above ViSi Mobile Monitoring Systems, knowing and intending that such systems would be used by customers and end users in a manner that infringes the RE218 patent. To that end, Sotera provides instructions and teachings to its customers and end users that such ViSi Mobile Monitoring Systems be used to infringe the RE218 patent. Sotera's acts and Foxconn's acts constitute infringement of the RE218 patent in violation of 35 U.S.C. § 271(b).
- 70. Upon information and belief, Sotera and Foxconn actively induce health-care service providers and users to directly infringe the asserted claims of the RE218 patent. By way of example only, upon information and belief, Sotera actively induces direct infringement of the RE218 patent by providing directions, demonstrations, guides, manuals, training for use, and/or other materials necessary for the use, refurbishing, and/or servicing of the ViSi

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- Upon information and belief, Sotera's acts and Foxconn's acts 71. constitute contributory infringement of the RE218 patent in violation of 35 U.S.C. Ş 271(c). Upon information and belief, Sotera and Foxconn contributorily infringe because, among other things, Sotera offers to sell and/or sells within the United States, and/or imports into the United States, components of the ViSi Mobile Monitoring System that constitute material parts of the invention of the asserted claims of the RE218 patent, are not staple articles or commodities of commerce suitable for substantial non-infringing use, and are known by Sotera and Foxconn to be especially made or especially adapted for use in an infringement of the RE218 patent.
- 72. Upon information and belief, Sotera's and Foxconn's infringement of the RE218 patent has been, and continues to be, willful, deliberate, and intentional by continuing its acts of infringement after becoming aware of the RE218 patent and its infringement thereof, thus acting in reckless disregard of Masimo's patent rights.
- As a consequence of Sotera's and Foxconn's infringement of the RE218 patent, Masimo has suffered and will continue to suffer irreparable harm and injury, including monetary damages in an amount to be determined at trial.
- Upon information and belief, unless enjoined, Sotera, Foxconn, and/or others acting on behalf of Sotera, will continue their infringing acts, thereby causing additional irreparable injury to Masimo for which there is no adequate remedy at law.

FIFTH CLAIM FOR RELIEF

(Infringement of U.S. Reissue Patent No. RE47,244)

Masimo realleges and reincorporates the allegations set forth in 75. paragraphs 1 through 74.

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- 76. Upon information and belief, Sotera products, including at least the ViSi Mobile Monitoring System products, infringe at least Claims 1-2, 6, 8, 9, 13-15, 18-26 of the RE244 patent under at least 35 U.S.C. § 271(a), (b), and (c).
- 77. Upon information and belief, Sotera has directly infringed one or more claims of the RE244 patent through manufacture use, sale, offer for sale, and/or importation into the United States of medical monitoring devices, including the ViSi Mobile Monitoring System.
- 78. Upon information and belief, Foxconn has directly infringed or induced Sotera and/or Sotera's customers to infringe one or more claims of the RE244 patent. For example, on information and belief Foxconn has directed Sotera to manufacture use, sell, offer for sale, and/or import into the United States, electronic patient monitoring systems, including the ViSi Mobile Monitoring System.
- For example, the ViSi Mobile Monitor of the ViSi Mobile Monitoring System includes all of the limitations of Claim 1 of the RE244 patent. The ViSi Mobile Monitoring System is a physiological measurement system including a ViSi Mobile Monitor. The ViSi Mobile Monitor includes a noninvasive physiological sensor at its thumb sensor configured to be positioned on a patient and output a signal responsive to a physiological condition of the patient. The ViSi Mobile Monitor includes one or more processors in communication with the noninvasive physiological sensor. The one or more processors of the ViSi Mobile Monitor is configured to electronically process the signal; responsive to processing the signal, determine a measurement of a physiological parameter based at least in part upon the signal; and determine that the measurement of the physiological parameter satisfies an alarm activation threshold. The one or more processors of the ViSi Mobile Monitor is also configured to electronically initiate a parameter-specific alarm delay or suspension period of time corresponding to the physiological parameter. The

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- parameter-specific alarm delay or suspension period of time is one of a plurality of parameter-specific alarm delay or suspension periods of time, and the parameter-specific alarm delay or suspension period of time is different from at least one other parameter-specific alarm delay or suspension period of time corresponding to at least one other physiological parameter for which the one or more processors are configured to determine at least one measurement. The one or more processors of the ViSi Mobile Monitor is configured to electronically activate an alarm for the physiological parameter in response to expiration of an amount of delay or suspension associated with the parameter-specific alarm delay or suspension period of time.
- 80. Upon information and belief, Sotera and Foxconn have monitored Masimo's patents, including the RE244 patent by hiring former Masimo employees and after previous trade secret misappropriation litigation asserted against Sotera by Masimo. Upon further information and belief, through the knowledge of the RE244 patent gained by monitoring Masimo's patents, Sotera and Foxconn knew or should have known that these activities would cause direct infringement. Sotera and Foxconn also had knowledge of the RE244 patent no later than the filing of this Complaint.
- 81. Upon information and belief, Sotera and Foxconn have actively induced others to infringe the RE244 patent by marketing and selling the above ViSi Mobile Monitoring Systems, knowing and intending that such systems would be used by customers and end users in a manner that infringes the RE244 patent. To that end, Sotera provides instructions and teachings to its customers and end users that such ViSi Mobile Monitoring Systems be used to infringe the RE244 patent. Sotera's acts and Foxconn's acts constitute infringement of the RE244 patent in violation of 35 U.S.C. § 271(b).
- 82. Upon information and belief, Sotera and Foxconn actively induce health-care service providers and users to directly infringe the asserted claims of

the RE244 patent. By way of example only, upon information and belief, Sotera actively induces direct infringement of the RE244 patent by providing directions, demonstrations, guides, manuals, training for use, and/or other materials necessary for the use, refurbishing, and/or servicing of the ViSi Mobile Monitor. Upon information and belief, Sotera and Foxconn knew or should have known that these activities would cause direct infringement.

- 83. Upon information and belief, Sotera's acts and Foxconn's acts constitute contributory infringement of the RE244 patent in violation of 35 U.S.C. § 271(c). Upon information and belief, Sotera and Foxconn contributorily infringe because, among other things, Sotera offers to sell and/or sells within the United States, and/or imports into the United States, components of the ViSi Mobile Monitoring System that constitute material parts of the invention of the asserted claims of the RE244 patent, are not staple articles or commodities of commerce suitable for substantial non-infringing use, and are known by Sotera and Foxconn to be especially made or especially adapted for use in an infringement of the RE244 patent.
- 84. Upon information and belief, Sotera's and Foxconn's infringement of the RE244 patent has been, and continues to be, willful, deliberate, and intentional by continuing its acts of infringement after becoming aware of the RE244 patent and its infringement thereof, thus acting in reckless disregard of Masimo's patent rights.
- 85. As a consequence of Sotera's and Foxconn's infringement of the RE244 patent, Masimo has suffered and will continue to suffer irreparable harm and injury, including monetary damages in an amount to be determined at trial.
- 86. Upon information and belief, unless enjoined, Sotera, Foxconn, and/or others acting on behalf of Sotera, will continue their infringing acts, thereby causing additional irreparable injury to Masimo for which there is no adequate remedy at law.

SIXTH CLAIM FOR RELIEF

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(Infringement of U.S. Reissue Patent No. RE47,249)

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87. Masimo realleges and reincorporates the allegations set forth in paragraphs 1 through 86.

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Upon information and belief, Sotera products, including at least the ViSi Mobile Monitoring System products, infringe at least Claims 1-2, 6-9, 13-15, and 18-24 of the RE249 patent under at least 35 U.S.C. § 271(a), (b), and (c).

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89. Upon information and belief, Sotera has directly infringed one or more claims of the RE249 patent through manufacture use, sale, offer for sale, and/or importation into the United States of medical monitoring devices, including the ViSi Mobile Monitoring System.

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90. Upon information and belief, Foxconn has directly infringed or induced Sotera and/or Sotera's customers to infringe one or more claims of the RE249 patent. For example, on information and belief Foxconn has directed Sotera to manufacture use, sell, offer for sale, and/or import into the United States, electronic patient monitoring systems, including the ViSi Mobile Monitoring System.

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91. For example, the ViSi Mobile Monitor of the ViSi Mobile Monitoring System includes all of the limitations of Claim 1 of the RE249

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patent. The ViSi Mobile Monitoring System is a physiological measurement system including a ViSi Mobile Monitor. The ViSi Mobile Monitor includes a

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noninvasive physiological sensor at its thumb sensor configured to be positioned

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on a patient and output a signal responsive to a physiological condition of the The ViSi Mobile Monitor includes one or more processors in patient.

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communication with the noninvasive physiological sensor. The one or more

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processors of the ViSi Mobile Monitor is configured to electronically determine

a measurement of a physiological parameter based at least in part upon the

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signal, and determine whether an alarm condition exists by determining whether an activation threshold has been satisfied by the measurement of the physiological parameter. The one or more processors of the ViSi Mobile Monitor is also configured to electronically access an alarm hold initiator for a parameter-specific alarm hold period of time corresponding to the physiological The parameter-specific alarm hold period of time is one of a parameter. plurality of parameter-specific alarm hold periods of time, and the parameterspecific alarm hold period of time is different from at least one other parameterspecific alarm hold period of time corresponding to at least one other physiological parameter for which the one or more processors are configured to determine at least one measurement. The one or more processors of the ViSi Mobile Monitor is configured to electronically determine that the alarm hold initiator indicates to hold an indication of an alarm for the alarm condition and, in response to determining that the alarm hold initiator indicates to hold the indication of the alarm, hold the indication of the alarm for the parameterspecific alarm hold period of time. The one or more processors of the ViSi Mobile Monitor is configured to electronically, subsequent to the parameterspecific alarm hold period of time passing, activate the indication of the alarm while the measurement of the physiological parameter satisfies the activation threshold.

92. Upon information and belief, Sotera and Foxconn have monitored Masimo's patents, including the RE249 patent by hiring former Masimo employees and after previous trade secret misappropriation litigation asserted against Sotera by Masimo. Upon further information and belief, through the knowledge of the RE249 patent gained by monitoring Masimo's patents, Sotera and Foxconn knew or should have known that these activities would cause direct infringement. Sotera and Foxconn also had knowledge of the RE249 patent no later than the filing of this Complaint.

- 93. Upon information and belief, Sotera and Foxconn have actively induced others to infringe the RE249 patent by marketing and selling the above ViSi Mobile Monitoring Systems, knowing and intending that such systems would be used by customers and end users in a manner that infringes the RE249 patent. To that end, Sotera provides instructions and teachings to its customers and end users that such ViSi Mobile Monitoring Systems be used to infringe the RE249 patent. Sotera's acts and Foxconn's acts constitute infringement of the RE249 patent in violation of 35 U.S.C. § 271(b).
- 94. Upon information and belief, Sotera and Foxconn actively induce health-care service providers and users to directly infringe the asserted claims of the RE249 patent. By way of example only, upon information and belief, Sotera actively induces direct infringement of the RE249 patent by providing directions, demonstrations, guides, manuals, training for use, and/or other materials necessary for the use, refurbishing, and/or servicing of the ViSi Mobile Monitor. Upon information and belief, Sotera and Foxconn knew or should have known that these activities would cause direct infringement.
- 95. Upon information and belief, Sotera's acts and Foxconn's acts constitute contributory infringement of the RE249 patent in violation of 35 U.S.C. § 271(c). Upon information and belief, Sotera and Foxconn contributorily infringe because, among other things, Sotera offers to sell and/or sells within the United States, and/or imports into the United States, components of the ViSi Mobile Monitoring System that constitute material parts of the invention of the asserted claims of the RE249 patent, are not staple articles or commodities of commerce suitable for substantial non-infringing use, and are known by Sotera and Foxconn to be especially made or especially adapted for use in an infringement of the RE249 patent.
- 96. Upon information and belief, Sotera's and Foxconn's infringement of the RE249 patent has been, and continues to be, willful, deliberate, and

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intentional by continuing its acts of infringement after becoming aware of the RE249 patent and its infringement thereof, thus acting in reckless disregard of Masimo's patent rights.

- 97. As a consequence of Sotera's and Foxconn's infringement of the RE249 patent, Masimo has suffered and will continue to suffer irreparable harm and injury, including monetary damages in an amount to be determined at trial.
- 98. Upon information and belief, unless enjoined, Sotera, Foxconn, and/or others acting on behalf of Sotera, will continue their infringing acts, thereby causing additional irreparable injury to Masimo for which there is no adequate remedy at law.

SEVENTH CLAIM FOR RELIEF (Infringement of U.S. Patent No. 10,213,108)

- 99. Masimo realleges and reincorporates the allegations set forth in paragraphs 1 through 98.
- 100. Upon information and belief, Sotera products, including at least the ViSi Mobile Monitoring System products, infringe at least Claims 1-22 of the '108 patent under at least 35 U.S.C. § 271(a), (b), and (c).
- 101. Upon information and belief, Sotera has directly infringed one or more claims of the '108 patent through manufacture use, sale, offer for sale, and/or importation into the United States of medical monitoring devices, including the ViSi Mobile Monitoring System.
- 102. Upon information and belief, Foxconn has directly infringed or induced Sotera and/or Sotera's customers to infringe one or more claims of the '108 patent. For example, on information and belief Foxconn has directed Sotera to manufacture use, sell, offer for sale, and/or import into the United States, electronic patient monitoring systems, including the ViSi Mobile Monitoring System.

103. For example, the ViSi Mobile Monitor of the ViSi Mobile Monitoring System includes all of the limitations of Claim 1 of the '108 patent. The ViSi Mobile Monitor is an arm mountable portable patient monitoring device configured to receive physiological information from a plurality of sensors attached to a patient at least two different measurement sites via wired connections for on-patient monitoring of parameter measurements and wireless transmission of parameter measurements to separate monitoring devices. The ViSi Mobile Monitor includes a housing configured to be secured to an arm of a patient under measurement. The ViSi Mobile Monitor includes a wrist strap mountable to a back side of the housing and configured to secure the housing to the arm of the patient. The ViSi Mobile Monitor includes a display positioned on a front side of the housing. The display of the ViSi Mobile Monitor is configured to show at least one status indicator of the portable patient monitoring device and one or more parameter measurements. The ViSi Mobile Monitor includes a first sensor port positioned on a first side of the housing and the first side of the housing is configured to face toward a hand of the arm of the patient when the housing is secured to the arm of the patient. The first sensor port of the ViSi Mobile Monitor is configured to electrically receive a signal from a thumb-type pulse oximetry sensor via a wired connection from the pulse oximetry sensor to the first sensor port. The wired connection is configured to extend from the first sensor port along a path substantially perpendicular to the first side of the housing. The ViSi Mobile Monitor also includes a second sensor port positioned on the housing and configured to receive a signal from a second sensor arrangement via a wired connection, and a third sensor port positioned on the housing configured to receive a signal from a third sensor arrangement via a wired connection. The ViSi Mobile Monitor includes one or more signal processing arrangements configured to receive the signal from the pulse oximetry sensor and cause to be displayed, on the display, at least

measurements of oxygen saturation and pulse rate derived from the signal. The ViSi Mobile Monitor includes a transmitter configured to wirelessly transmit information indicative of the measurements of oxygen saturation and pulse rate to a separate monitoring device configured to receive the information indicative of the measurements of oxygen saturation and pulse rate.

104. Upon information and belief, Sotera and Foxconn have monitored Masimo's patents, including the '108 patent by hiring former Masimo employees and after previous trade secret misappropriation litigation asserted against Sotera by Masimo. Upon further information and belief, through the knowledge of the '108 patent gained by monitoring Masimo's patents, Sotera and Foxconn knew or should have known that these activities would cause direct infringement. Sotera and Foxconn also had knowledge of the '108 patent no later than the filing of this Complaint.

105. Upon information and belief, Sotera and Foxconn have actively induced others to infringe the '108 patent by marketing and selling the above ViSi Mobile Monitoring Systems, knowing and intending that such systems would be used by customers and end users in a manner that infringes the '108 patent. To that end, Sotera provides instructions and teachings to its customers and end users that such ViSi Mobile Monitoring Systems be used to infringe the '108 patent. Sotera's acts and Foxconn's acts constitute infringement of the '108 patent in violation of 35 U.S.C. § 271(b).

106. Upon information and belief, Sotera and Foxconn actively induce health-care service providers and users to directly infringe the asserted claims of the '108 patent. By way of example only, upon information and belief, Sotera actively induces direct infringement of the '108 patent by providing directions, demonstrations, guides, manuals, training for use, and/or other materials necessary for the use, refurbishing, and/or servicing of the ViSi Mobile Monitor.

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that these activities would cause direct infringement. 107. Upon information and belief, Sotera's acts and Foxconn's acts

Upon information and belief, Sotera and Foxconn knew or should have known

- constitute contributory infringement of the '108 patent in violation of 35 U.S.C. Upon information and belief, Sotera and Foxconn contributorily § 271(c). infringe because, among other things, Sotera offers to sell and/or sells within the United States, and/or imports into the United States, components of the ViSi Mobile Monitoring System that constitute material parts of the invention of the asserted claims of the '108 patent, are not staple articles or commodities of commerce suitable for substantial non-infringing use, and are known by Sotera and Foxconn to be especially made or especially adapted for use in an infringement of the '108 patent.
- 108. Upon information and belief, Sotera's and Foxconn's infringement of the '108 patent has been, and continues to be, willful, deliberate, and intentional by continuing its acts of infringement after becoming aware of the '108 patent and its infringement thereof, thus acting in reckless disregard of Masimo's patent rights.
- 109. As a consequence of Sotera's and Foxconn's infringement of the '108 patent, Masimo has suffered and will continue to suffer irreparable harm and injury, including monetary damages in an amount to be determined at trial.
- 110. Upon information and belief, unless enjoined, Sotera, Foxconn, and/or others acting on behalf of Sotera, will continue their infringing acts, thereby causing additional irreparable injury to Masimo for which there is no adequate remedy at law.

EIGHTH CLAIM FOR RELIEF (Infringement of U.S. Patent No. 10,255,994)

111. Masimo realleges and reincorporates the allegations set forth in paragraphs 1 through 110.

- 112. Upon information and belief, Sotera products, including at least the ViSi Mobile Monitoring System products, infringe at least Claims 1-8 of the '994 patent under at least 35 U.S.C. § 271(a), (b), and (c).
- 113. Upon information and belief, Sotera has directly infringed one or more claims of the '994 patent through manufacture use, sale, offer for sale, and/or importation into the United States of medical monitoring devices, including the ViSi Mobile Monitoring System.
- 114. Upon information and belief, Foxconn has directly infringed or induced Sotera and/or Sotera's customers to infringe one or more claims of the '994 patent. For example, on information and belief Foxconn has directed Sotera to manufacture use, sell, offer for sale, and/or import into the United States, electronic patient monitoring systems, including the ViSi Mobile Monitoring System.
- 115. For example, the ViSi Mobile Monitor of the ViSi Mobile Monitoring System includes all of the limitations of Claim 1 of the '994 patent. The ViSi Mobile Monitoring System is a system configured to reduce a frequency of alarms from a physiological monitoring system. The ViSi Mobile Monitoring System includes a ViSi Mobile Monitor having a physiological sensor configured to detect signals representative of a physiological condition of a patient. The ViSi Mobile Monitor includes one or more processors configured to receive the detected signals and determine a physiological parameter of the patient. The one or more processors of the ViSi Mobile Monitor is further configured to detect an alarm condition for the physiological parameter and delay a notification of the alarm condition until the alarm condition persists for a predetermined alarm notification delay time. The one or more processors of the ViSi Mobile Monitor is configured to provide a notification of the alarm condition responsive to the alarm condition persisting through the alarm notification delay time. The one or more processors of the ViSi Mobile Monitor

is associated with a care unit. The ViSi Mobile Monitor also includes a reporting module configured to simulate, using measurements obtained from the care unit, different alarm notification delay times to determine whether any of the different alarm notification delay times would have resulted in an alarm notification event. The alarm notification event for each different alarm notification delay time indicates that an alarm condition persisted for at least that alarm notification delay time. The reporting module of the ViSi Mobile Monitor is configured to provide an indicator of the effect of a change in alarm notification delay time on frequency of alarm notification events. The indicator is indicative of a change in the alarm notification delay time that is effective to reduce the frequency of transient or false alarms. The indicator is configured to be used to program one or more physiological monitoring systems with alarm notification delay times.

116. Upon information and belief, Sotera and Foxconn have monitored Masimo's patents, including the '994 patent by hiring former Masimo employees and after previous trade secret misappropriation litigation asserted against Sotera by Masimo. Upon further information and belief, through the knowledge of the '994 patent gained by monitoring Masimo's patents, Sotera and Foxconn knew or should have known that these activities would cause direct infringement. Sotera and Foxconn also had knowledge of the '994 patent no later than the filing of this Complaint.

117. Upon information and belief, Sotera and Foxconn have actively induced others to infringe the '994 patent by marketing and selling the above ViSi Mobile Monitoring Systems, knowing and intending that such systems would be used by customers and end users in a manner that infringes the '994 patent. To that end, Sotera provides instructions and teachings to its customers and end users that such ViSi Mobile Monitoring Systems be used to infringe the

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26 27 28 '994 patent. Sotera's acts and Foxconn's acts constitute infringement of the '994 patent in violation of 35 U.S.C. § 271(b).

- 118. Upon information and belief, Sotera and Foxconn actively induce health-care service providers and users to directly infringe the asserted claims of the '994 patent. By way of example only, upon information and belief, Sotera actively induces direct infringement of the '994 patent by providing directions, demonstrations, guides, manuals, training for use, and/or other materials necessary for the use, refurbishing, and/or servicing of the ViSi Mobile Monitor. Upon information and belief, Sotera and Foxconn knew or should have known that these activities would cause direct infringement.
- 119. Upon information and belief, Sotera's acts and Foxconn's acts constitute contributory infringement of the '994 patent in violation of 35 U.S.C. Upon information and belief, Sotera and Foxconn contributorily § 271(c). infringe because, among other things, Sotera offers to sell and/or sells within the United States, and/or imports into the United States, components of the ViSi Mobile Monitoring System that constitute material parts of the invention of the asserted claims of the '994 patent, are not staple articles or commodities of commerce suitable for substantial non-infringing use, and are known by Sotera and Foxconn to be especially made or especially adapted for use in an infringement of the '994 patent.
- 120. Upon information and belief, Sotera's and Foxconn's infringement of the '994 patent has been, and continues to be, willful, deliberate, and intentional by continuing its acts of infringement after becoming aware of the '994 patent and its infringement thereof, thus acting in reckless disregard of Masimo's patent rights.
- 121. As a consequence of Sotera's and Foxconn's infringement of the '994 patent, Masimo has suffered and will continue to suffer irreparable harm and injury, including monetary damages in an amount to be determined at trial.

122. Upon information and belief, unless enjoined, Sotera, Foxconn, and/or others acting on behalf of Sotera, will continue their infringing acts, thereby causing additional irreparable injury to Masimo for which there is no adequate remedy at law.

NINTH CLAIM FOR RELIEF

(Infringement of U.S. Patent No. RE47,353)

- 123. Masimo realleges and reincorporates the allegations set forth in paragraphs 1 through 122.
- 124. Upon information and belief, Sotera products, including at least the ViSi Mobile Monitoring System products, infringe at least Claims 1-2, 5-9, 13-15, 18-25 of the RE353 patent under at least 35 U.S.C. § 271(a), (b), and (c).
- 125. Upon information and belief, Sotera has directly infringed one or more claims of the RE353 patent through manufacture use, sale, offer for sale, and/or importation into the United States of medical monitoring devices, including the ViSi Mobile Monitoring System.
- 126. Upon information and belief, Foxconn has directly infringed or induced Sotera and/or Sotera's customers to infringe one or more claims of the RE353 patent. For example, on information and belief Foxconn has directed Sotera to manufacture use, sell, offer for sale, and/or import into the United States, electronic patient monitoring systems, including the ViSi Mobile Monitoring System.
- 127. For example, the ViSi Mobile Monitor of the ViSi Mobile Monitoring System includes all of the limitations of Claim 1 of the RE353 patent. The ViSi Mobile Monitor system is a physiological measurement system including a ViSi Mobile Monitor. The ViSi Mobile Monitor includes a noninvasive physiological sensor at its thumb sensor configured to be positioned on a patient and output a signal responsive to a physiological condition of the patient. The ViSi Mobile Monitor includes one or more processors in

communication with the noninvasive physiological sensor. The one or more processors of the ViSi Mobile Monitor is configured to electronically process the signal to determine a measurement of a physiological parameter based at least in part upon the signal and determine that an alarm should be activated in response to the measurement of the physiological parameter satisfying an alarm activation threshold. The one or more processors of the ViSi Mobile Monitor is also configured to electronically determine that an alarm suspension should be initiated for a parameter-specific alarm suspension period of time corresponding to the physiological parameter. The parameter-specific alarm suspension period of time is one of at least a plurality of parameter-specific alarm suspension periods of time, and the parameter-specific alarm suspension period of time is different from at least one other parameter-specific alarm suspension period of time corresponding to at least one other physiological parameter for which the one or more processors are configured to determine at least one measurement. The one or more processors of the ViSi Mobile Monitor is configured to electronically suspend the alarm for the parameter-specific alarm suspension period of time and activate the alarm when the measurement of the physiological parameter satisfies the alarm activation threshold after the parameter-specific alarm suspension period of time has passed.

128. Upon information and belief, Sotera and Foxconn have monitored Masimo's patents, including the RE353 patent by hiring former Masimo employees and after previous trade secret misappropriation litigation asserted against Sotera by Masimo. Upon further information and belief, through the knowledge of the RE353 patent gained by monitoring Masimo's patents, Sotera and Foxconn knew or should have known that these activities would cause direct infringement. Sotera and Foxconn also had knowledge of the RE353 patent no later than the filing of this Complaint.

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- 129. Upon information and belief, Sotera and Foxconn have actively induced others to infringe the RE353 patent by marketing and selling the above ViSi Mobile Monitoring Systems, knowing and intending that such systems would be used by customers and end users in a manner that infringes the RE353 patent. To that end, Sotera provides instructions and teachings to its customers and end users that such ViSi Mobile Monitoring Systems be used to infringe the RE353 patent. Sotera's acts and Foxconn's acts constitute infringement of the RE353 patent in violation of 35 U.S.C. § 271(b).
- 130. Upon information and belief, Sotera and Foxconn actively induce health-care service providers and users to directly infringe the asserted claims of the RE353 patent. By way of example only, upon information and belief, Sotera and Foxconn actively induce direct infringement of the RE353 patent by providing directions, demonstrations, guides, manuals, training for use, and/or other materials necessary for the use, refurbishing, and/or servicing of the ViSi Mobile Monitor. Upon information and belief, Sotera and Foxconn knew or should have known that these activities would cause direct infringement.
- 131. Upon information and belief, Sotera's acts and Foxconn's acts constitute contributory infringement of the RE353 patent in violation of 35 U.S.C. § 271(c). Upon information and belief, Sotera contributorily infringes because, among other things, Sotera offers to sell and/or sells within the United States, and/or imports into the United States, components of the ViSi Mobile Monitoring System that constitute material parts of the invention of the asserted claims of the RE353 patent, are not staple articles or commodities of commerce suitable for substantial non-infringing use, and are known by Sotera and Foxconn to be especially made or especially adapted for use in an infringement of the RE353 patent.
- 132. Upon information and belief, Sotera's and Foxconn's infringement of the RE353 patent has been, and continues to be, willful, deliberate, and

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intentional by continuing its acts of infringement after becoming aware of the RE353 patent and its infringement thereof, thus acting in reckless disregard of Masimo's patent rights.

- 133. As a consequence of Sotera's and Foxconn's infringement of the RE353 patent, Masimo has suffered and will continue to suffer irreparable harm and injury, including monetary damages in an amount to be determined at trial.
- 134. Upon information and belief, unless enjoined, Sotera, Foxconn, and/or others acting on behalf of Sotera, will continue their infringing acts, thereby causing additional irreparable injury to Masimo for which there is no adequate remedy at law.

IX. PRAYER FOR RELIEF

WHEREFORE, Plaintiff Masimo prays for judgment and seeks relief as follows:

- (1) Pursuant to 35 U.S.C. § 271, a determination that Sotera, Foxconn, and their officers, agents, servants, employees, attorneys and all others in active concert and/or participation with them have infringed each of the '735, '300, '623, RE218, RE244, RE249, '108, '994, and RE353 patents through the manufacture, use, importation, offer for sale, and/or sale of infringing products and/or any of the other acts prohibited by 35 U.S.C. § 271;
- Pursuant to 35 U.S.C. § 283, an injunction enjoining Sotera, (2) Foxconn, and their officers, agents, servants, employees, attorneys and all others in active concert and/or participation with them from infringing the '735, '300, '623, RE218, RE244, RE249, '108, '994, and RE353 patents through the manufacture, use, importation, offer for sale, and/or sale of infringing products and/or any of the other acts prohibited by 35 U.S.C. § 271, including preliminary and permanent injunctive relief;
- Pursuant to 35 U.S.C. § 284, an award of compensating Masimo (3)for Sotera's and Foxconn's infringement of the '735, '300, '623, RE218,

RE244, RE249, '108, '994, and RE353 patents through payment of not less than a reasonable royalty on Sotera's sales of infringing products;

- (4) Pursuant to 35 U.S.C. § 284, an award increasing damages up to three times the amount found or assessed by the jury for Sotera's and Foxconn's infringement of each of the '735, '300, '623, RE218, RE244, RE249, '108, '994, and RE353 patents in view of the willful and deliberate nature of the infringement;
- (5) Pursuant to 35 U.S.C. § 285, a finding that this is an exceptional case, and an award of reasonable attorneys' fees and non-taxable costs;
- (6) An assessment of prejudgment and post-judgment interest and costs against Sotera and Foxconn, together with an award of such interest and costs, pursuant to 35 U.S.C. § 284;
 - (7) An award of taxable costs; and
- (8) That Masimo be granted such other and further relief as the Court deems equitable and just in the circumstances.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: June 12, 2019 By: /s/ Brian C. Claassen

Joseph R. Re Stephen C. Jensen Irfan A. Lateef Brian C. Claassen

Attorneys for Plaintiff
MASIMO CORPORATION

DEMAND FOR JURY TRIAL Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Plaintiff Masimo Corporation demands a trial by jury of all issues raised by the pleadings which are triable by jury. Respectfully submitted, KNOBBE, MARTENS, OLSON & BEAR, LLP Dated: June 12, 2019 By: /s/ Brian C. Claassen Joseph R. Re Stephen C. Jensen Irfan A. Lateef Brian C. Claassen Attorneys for Plaintiff MASIMO CORPORATION

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US009788735B2

(12) United States Patent

(10) Patent No.: US 9,788,735 B2

(45) **Date of Patent:** *Oct. 17, 2017

(54) BODY WORN MOBILE MEDICAL PATIENT MONITOR

(71) Applicant: MASIMO CORPORATION, Irvine,

CA (US)

(72) Inventor: Ammar Al-Ali, San Juan Capistrano,

CA (US)

(73) Assignee: MASIMO CORPORATION, Irvine,

CA (US)

(*) Notice: Subject to any disclaimer, the term of this

patent is extended or adjusted under 35

U.S.C. 154(b) by 0 days.

This patent is subject to a terminal dis-

claimer.

(21) Appl. No.: 15/499,619

(22) Filed: **Apr. 27, 2017**

(65) Prior Publication Data

US 2017/0224233 A1 Aug. 10, 2017

Related U.S. Application Data

(63) Continuation of application No. 15/448,989, filed on Mar. 3, 2017, which is a continuation of application (Continued)

(51) **Int. Cl. A61B 5/1455**

A61B 5/0205

(2006.01) (2006.01)

(Continued)

(52) U.S. Cl.

CPC A61B 5/0205 (2013.01); A61B 5/0214 (2013.01); A61B 5/021 (2013.01);

(Continued)

(58) Field of Classification Search

CPC ... A61B 5/0002; A61B 5/0004; A61B 5/0024; A61B 5/02; A61B 5/0205; A61B 5/0402; (Continued)

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Primary Examiner — Eric Winakur

(74) Attorney, Agent, or Firm — Knobbe Martens Olson & Bear LLP

(57) ABSTRACT

A body worn mobile medical monitoring device configured to minimize cable wiring from a sensor by placement of one or more sensor communication ports. The body worn mobile medical monitoring device includes a housing securable on a lower arm of a patient, a display, and a sensor communication port positioned on a side of the housing and configured to face a hand of the lower arm of the patient when the mobile medical monitoring device is mounted to the lower arm of the patient. The sensor communication port provides wired communication with a pulse oximetry sensor attached to a digit of the hand of the patient, and is positioned on the side of the housing such that a path from the port on the side of the housing to the digit of the patient is shorter than any other path from any other side of the housing to the digit.

20 Claims, 17 Drawing Sheets

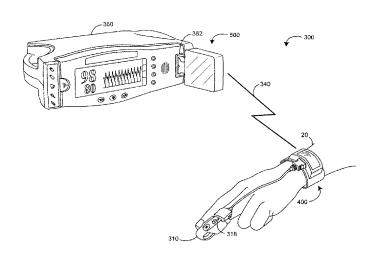


Exhibit 1

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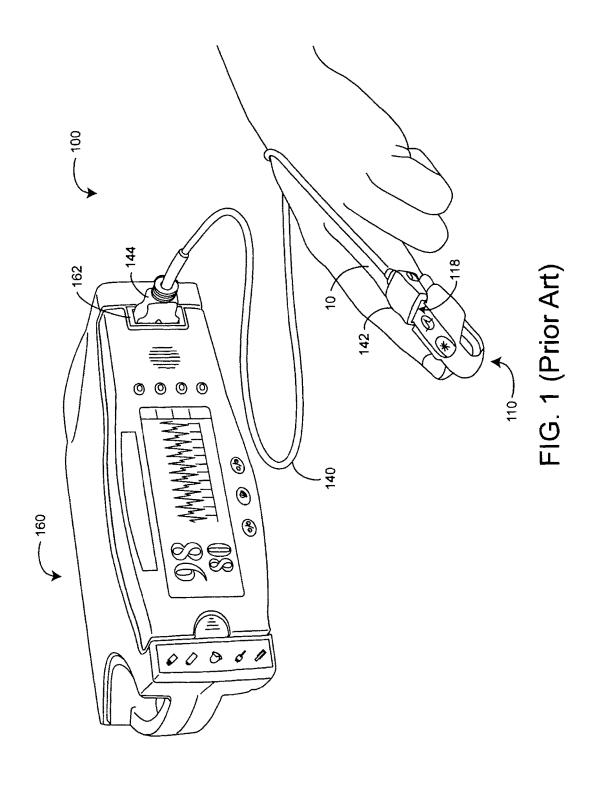
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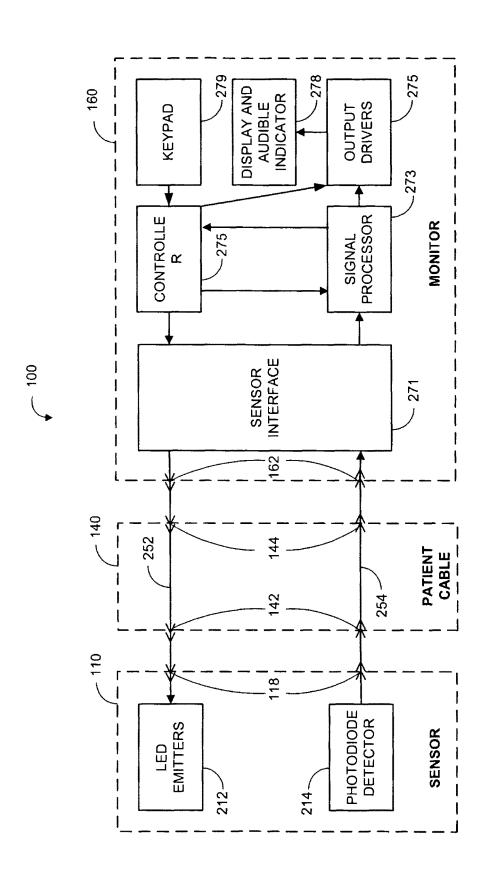
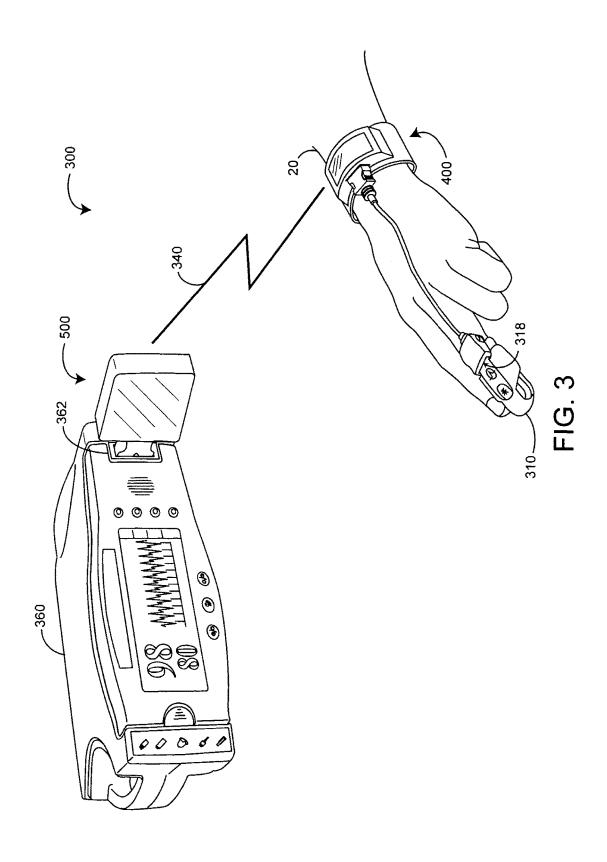


FIG. 2 (Prior Art)

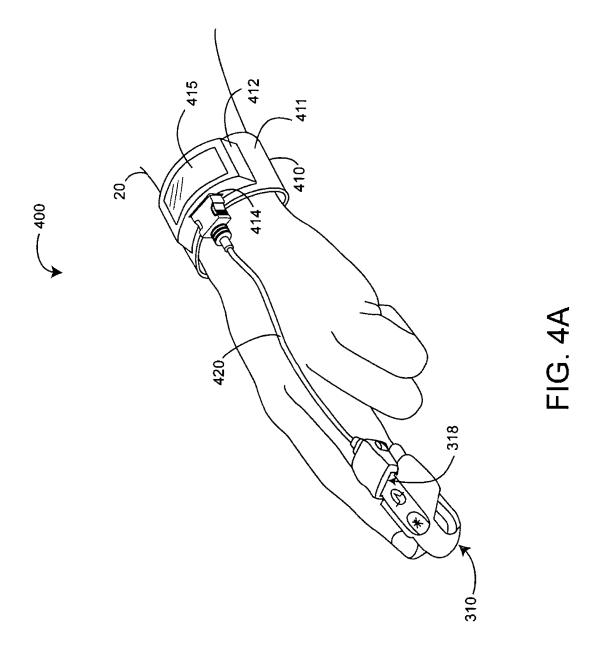
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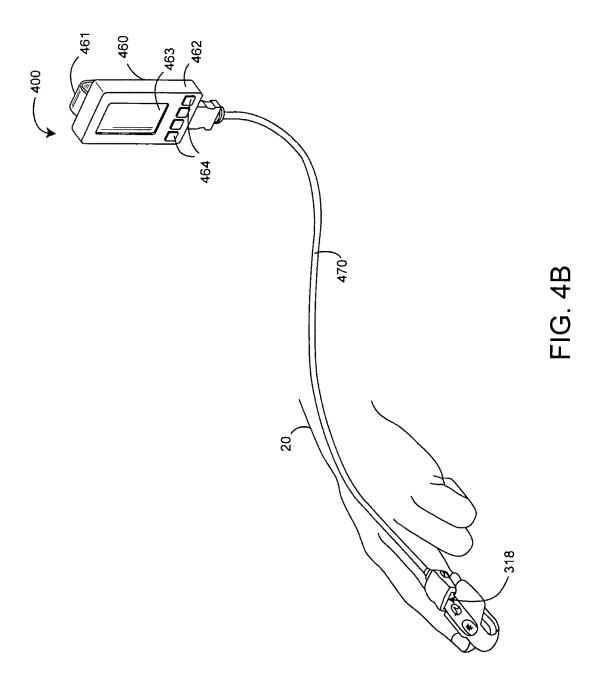
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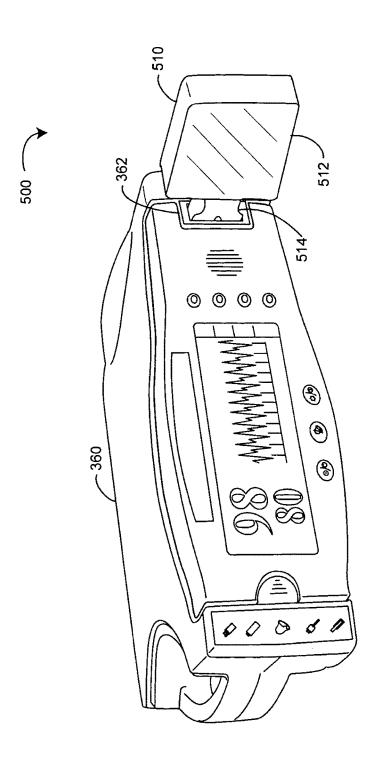


FIG. 5/

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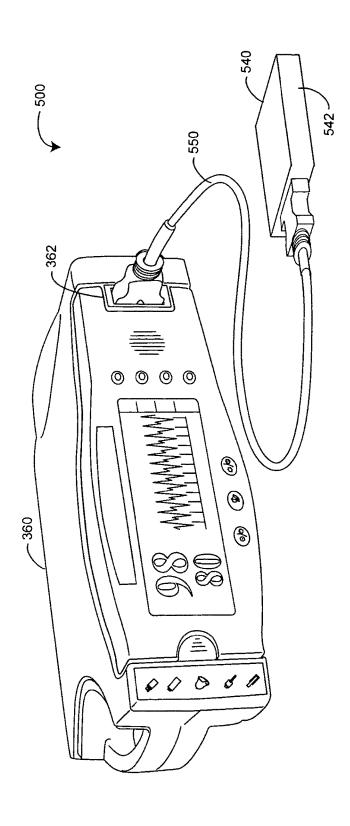
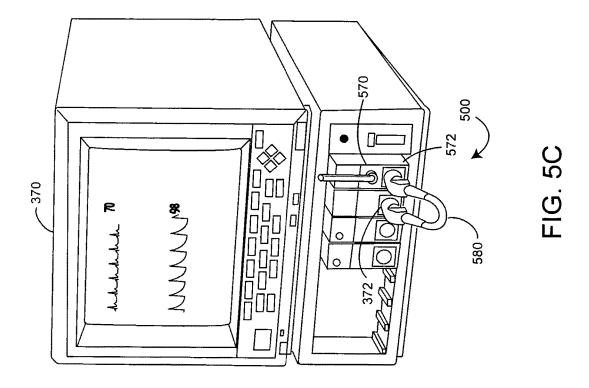


FIG. 5E

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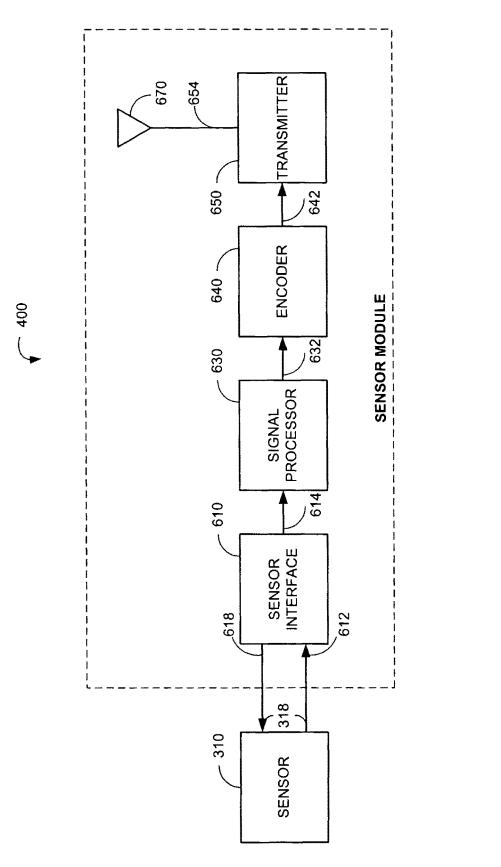


FIG.

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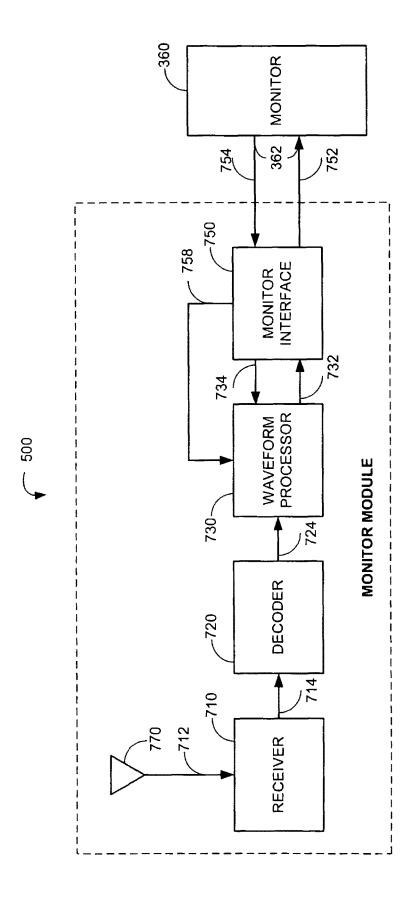


FIG. 7

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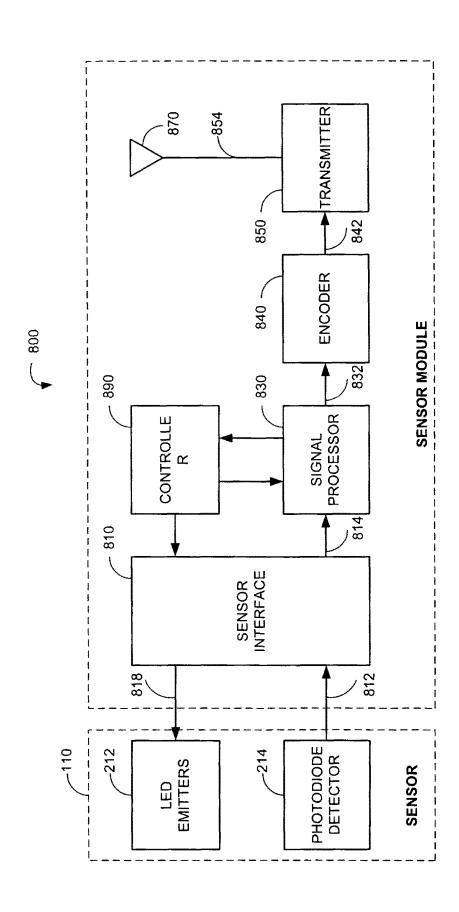


FIG. 8

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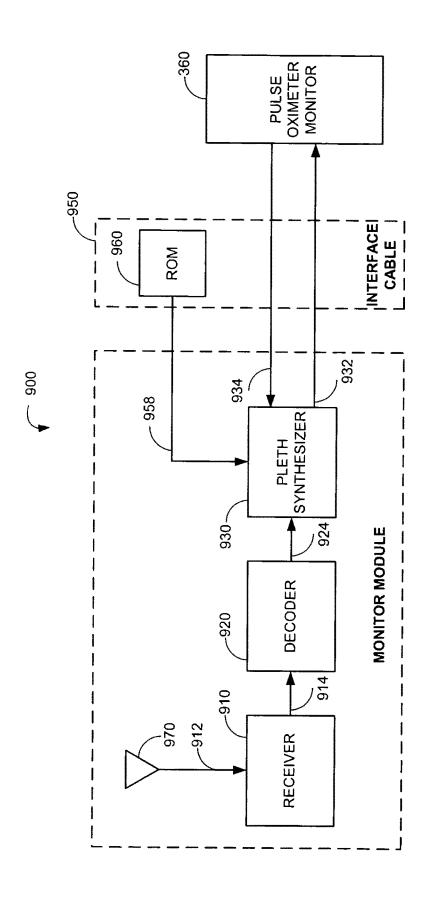


FIG. 9

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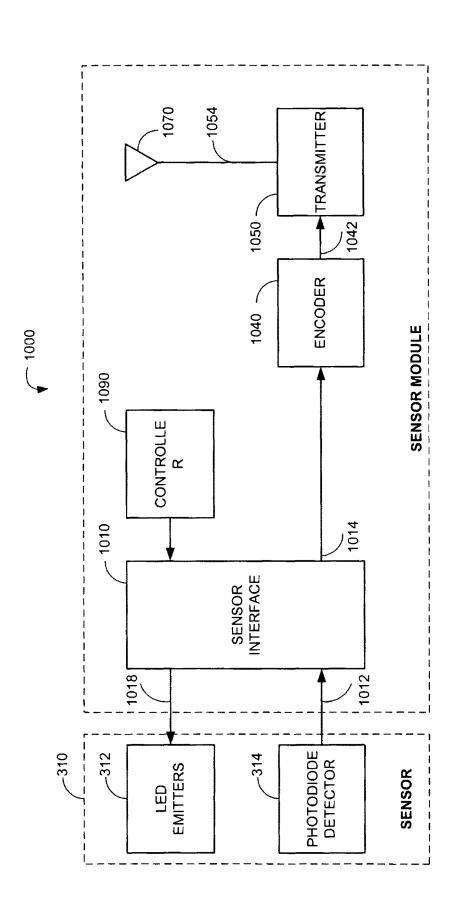


FIG. 10

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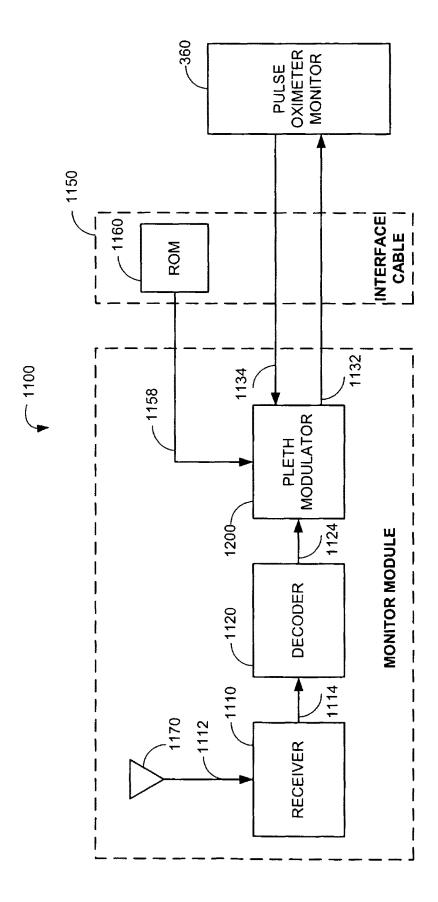
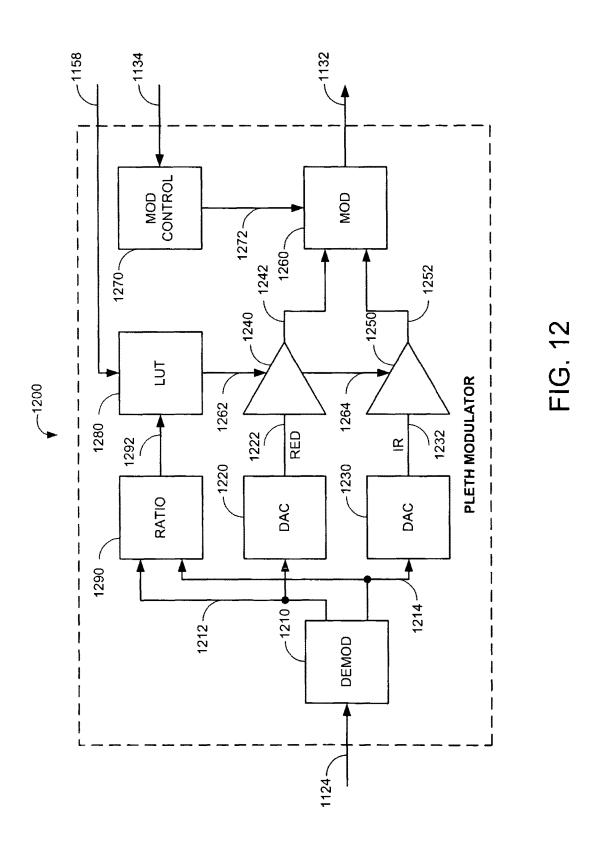


FIG. 11

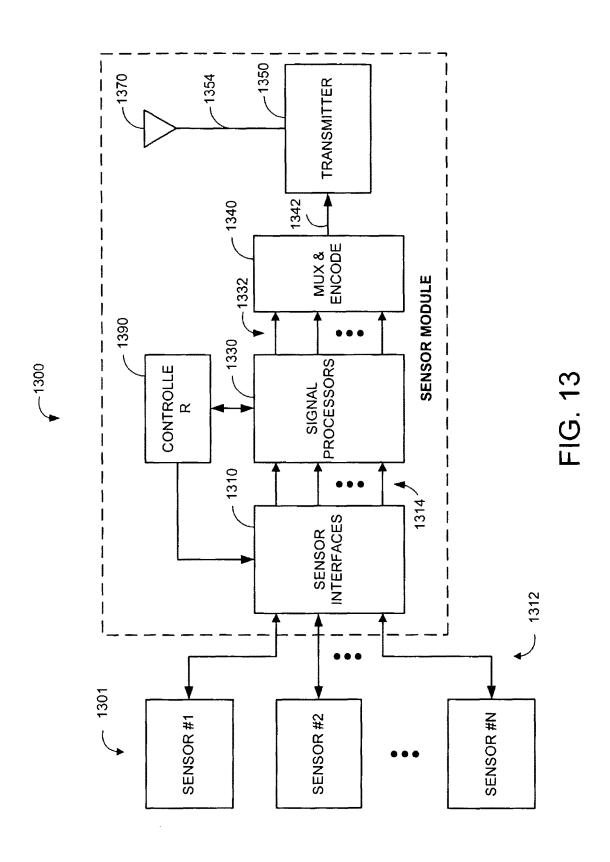
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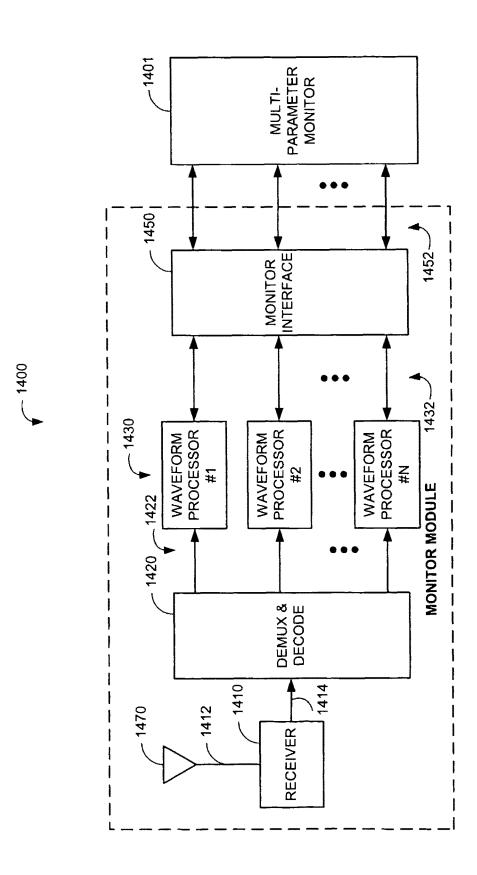


FIG. 14

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BODY WORN MOBILE MEDICAL PATIENT MONITOR

REFERENCE TO RELATED APPLICATION

The present application is a continuation of U.S. patent application Ser. No. 15/448,989, filed on Mar. 3, 2017, entitled "Physiological Measurement Communications Adapter," which is a continuation of U.S. patent application Ser. No. 14/815,232, filed on Jul. 31, 2015, entitled "Physi-10" ological Measurement Communications Adapter," which is a continuation of U.S. patent application Ser. No. 14/217, 788, filed on Mar. 18, 2014, entitled "Wrist-Mounted Physiological Measurement Device," now U.S. Pat. No. 9,113, 832, which is a continuation of U.S. patent application Ser. 15 No. 14/037,137, filed on Sep. 25, 2013, entitled "Physiological Measurement Communications Adapter," now U.S. Pat. No. 9,113,831, which is a continuation of U.S. patent application Ser. No. 12/955,826, filed on Nov. 29, 2010, entitled "Physiological Measurement Communications 20 Adapter," now U.S. Pat. No. 8,548,548, which is a continuation of U.S. patent application Ser. No. 11/417,006, filed on May 3, 2006, entitled "Physiological Measurement Communications Adapter," now U.S. Pat. No. 7,844,315, which claims priority benefit under 35 U.S.C. §120 to, and is a 25 continuation of, U.S. patent application Ser. No. 11/048,330, filed Feb. 1, 2005, entitled "Physiological Measurement Communications Adapter," now U.S. Pat. No. 7,844,314, which is a continuation of U.S. patent application Ser. No. 10/377,933, entitled "Physiological Measurement Commu-30 nications Adapter," now U.S. Pat. No. 6,850,788, which claims priority benefit under 35 U.S.C. §119(e) from U.S. Provisional Application No. 60/367,428, filed Mar. 25, 2002, entitled "Physiological Measurement Communications Adapter." The present application also incorporates the 35 foregoing utility disclosures herein by reference.

BACKGROUND OF THE INVENTION

of blood oxygen, blood pressure, respiratory gas, and EKG among other parameters. Each of these physiological parameters typically requires a sensor in contact with a patient and a cable connecting the sensor to a monitoring device. For example, FIGS. 1-2 illustrate a conventional pulse oximetry 45 system 100 used for the measurement of blood oxygen. As shown in FIG. 1, a pulse oximetry system has a sensor 110. a patient cable 140 and a monitor 160. The sensor 110 is typically attached to a finger 10 as shown. The sensor 110 has a plug 118 that inserts into a patient cable socket 142. 50 The monitor 160 has a socket 162 that accepts a patient cable plug 144. The patient cable 140 transmits an LED drive signal 252 (FIG. 2) from the monitor 160 to the sensor 110 and a resulting detector signal 254 (FIG. 2) from the sensor 110 to the monitor 160. The monitor 160 processes the 55 detector signal 254 (FIG. 2) to provide, typically, a numerical readout of the patient's oxygen saturation, a numerical readout of pulse rate, and an audible indicator or "beep" that occurs in response to each arterial pulse.

As shown in FIG. 2, the sensor 110 has both red and 60 infrared LED emitters 212 and a photodiode detector 214. The monitor 160 has a sensor interface 271, a signal processor 273, a controller 275, output drivers 276, a display and audible indicator 278, and a keypad 279. The monitor 160 determines oxygen saturation by computing the differ- 65 ential absorption by arterial blood of the two wavelengths emitted by the sensor emitters 212, as is well-known in the

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art. The sensor interface 271 provides LED drive current 252 which alternately activates the red and IR LED emitters 212. The photodiode detector 214 generates a signal 254 corresponding to the red and infrared light energy attenuated from transmission through the patient finger 10 (FIG. 1). The sensor interface 271 also has input circuitry for amplification, filtering and digitization of the detector signal 254. The signal processor 273 calculates a ratio of detected red and infrared intensities, and an arterial oxygen saturation value is empirically determined based on that ratio. The controller 275 provides hardware and software interfaces for managing the display and audible indicator 278 and keypad 279. The display and audible indicator 278 shows the computed oxygen status, as described above, and provides the pulse beep as well as alarms indicating oxygen desaturation events. The keypad 279 provides a user interface for setting alarm thresholds, alarm enablement, and display options, to name a few.

SUMMARY OF THE INVENTION

Conventional physiological measurement systems are limited by the patient cable connection between sensor and monitor. A patient must be located in the immediate vicinity of the monitor. Also, patient relocation requires either disconnection of monitoring equipment and a corresponding loss of measurements or an awkward simultaneous movement of patient equipment and cables. Various devices have been proposed or implemented to provide wireless communication links between sensors and monitors, freeing patients from the patient cable tether. These devices, however, are incapable of working with the large installed base of existing monitors and sensors, requiring caregivers and medical institutions to suffer expensive wireless upgrades. It is desirable, therefore, to provide a communications adapter that is plug-compatible both with existing sensors and monitors and that implements a wireless link replacement for the patient cable.

An aspect of a physiological measurement communica-Patient vital sign monitoring may include measurements 40 tions adapter comprises a sensor interface configured to receive a sensor signal. A transmitter modulates a first baseband signal responsive to the sensor signal so as to generate a transmit signal. A receiver demodulates a receive signal corresponding to the transmit signal so as to generate a second baseband signal corresponding to the first baseband signal. Further, a monitor interface is configured to communicate a waveform responsive to the second baseband signal to a sensor port of a monitor. The waveform is adapted to the monitor so that measurements derived by the monitor from the waveform are generally equivalent to measurements derivable from the sensor signal. The communications adapter may further comprise a signal processor having an input in communications with the sensor interface, where the signal processor is operable to derive a parameter responsive to the sensor signal and where the first baseband signal is responsive to the parameter. The parameter may correspond to at least one of a measured oxygen saturation and a pulse rate.

One embodiment may further comprise a waveform generator that synthesizes the waveform from a predetermined shape. The waveform generator synthesizes the waveform at a frequency adjusted to be generally equivalent to the pulse rate. The waveform may have a first amplitude and a second amplitude, and the waveform generator may be configured to adjusted the amplitudes so that measurements derived by the monitor are generally equivalent to a measured oxygen saturation.

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In another embodiment, the sensor interface is operable on the sensor signal to provide a plethysmograph signal output, where the first baseband signal is responsive to the plethysmograph signal. This embodiment may further comprise a waveform modulator that modifies a decoded signal responsive to the second baseband signal to provide the waveform. The waveform modulator may comprise a demodulator that separates a first signal and a second signal from the decoded signal, an amplifier that adjusts amplitudes of the first and second signals to generate a first adjusted signal and a second adjusted signal, and a modulator that combines the first and second adjusted signals into the waveform. The amplitudes of the first and second signals may be responsive to predetermined calibration data for the sensor and the monitor.

An aspect of a physiological measurement communications adapter method comprises the steps of inputting a sensor signal at a patient location, communicating patient data derived from the sensor signal between the patient location and a monitor location, constructing a waveform at the monitor location responsive to the sensor signal, and 20 providing the waveform to a monitor via a sensor port. The waveform is constructed so that the monitor calculates a parameter generally equivalent to a measurement derivable from the sensor signal.

In one embodiment, the communicating step may com- 25 prise the substeps of deriving a conditioned signal from the sensor signal, calculating a parameter signal from the conditioned signal, and transmitting the parameter signal from the patient location to the monitor location. The constructing step may comprise the substep of synthesizing the waveform 30 from the parameter signal. In an alternative embodiment, the communicating step may comprise the substeps of deriving a conditioned signal from said sensor signal and transmitting the conditioned signal from the patient location to the monitor location. The constructing step may comprise the 35 substeps of demodulating the conditioned signal and remodulating the conditioned signal to generate the waveform. The providing step may comprise the substeps of inputting a monitor signal from an LED drive output of the sensor port, modulating the waveform in response to the monitor 40 signal, and outputting the waveform on a detector input of the sensor port.

Another aspect of a physiological measurement communications adapter comprises a sensor interface means for inputting a sensor signal and outputting a conditioned signal, 45 a transmitter means for sending data responsive to the sensor signal, and a receiver means for receiving the data. The communications adapter further comprises a waveform processor means for constructing a waveform from the data so that measurements derived by a monitor from the waveform 50 are generally equivalent to measurements derivable from the sensor signal, and a monitor interface means for communicating the waveform to a sensor port of the monitor. The communications adapter may further comprise a signal processor means for deriving a parameter signal from the 55 conditioned signal, where the data comprises the parameter signal. The waveform processor means may comprise a means for synthesizing the waveform from the parameter signal. The data may comprise the conditioned signal, and the waveform processor means may comprise a means for 60 modulating the conditioned signal in response to the monitor.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is an illustration of a prior art pulse oximetry system:

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FIG. 2 is a functional block diagram of a prior art pulse oximetry system;

FIG. 3 is an illustration of a physiological measurement communications adapter;

FIGS. 4A-B are illustrations of communications adapter sensor modules;

FIGS. **5**A-C are illustrations of communications adapter monitor modules;

FIG. 6 is a functional block diagram of a communications adapter sensor module;

FIG. 7 is a functional block diagram of a communications adapter monitor module;

FIG. **8** is a functional block diagram of a sensor module configured to transmit measured pulse oximeter parameters;

FIG. 9 is a functional block diagram of a monitor module configured to received measured pulse oximeter parameters;

FIG. 10 is a functional block diagram of a sensor module configured to transmit a plethysmograph;

FIG. 11 is a functional block diagram of a monitor module configured to receive a plethysmograph;

FIG. 12 is a functional block diagram of a waveform modulator:

FIG. 13 is a functional block diagram of a sensor module configured for multiple sensors; and

FIG. 14 is a functional block diagram of a monitor module configured for multiple sensors.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Overview

FIG. 3 illustrates one embodiment of a communications adapter. FIGS. 4-5 illustrate physical configurations for a communications adapter. In particular, FIGS. 4A-B illustrate sensor module configurations and FIGS. 5A-C illustrate monitor module configurations. FIGS. 6-14 illustrate communications adapter functions. In particular, FIGS. 6-7 illustrate general functions for a sensor module and a monitor module, respectively. FIGS. 8-9 functionally illustrate a communications adapter where derived pulse oximetry parameters, such as saturation and pulse rate are transmitted between a sensor module and a monitor module. Also, FIGS. 10-12 functionally illustrate a communications adapter where a plethysmograph is transmitted between a sensor module and a monitor module. FIGS. 13-14 functionally illustrate a multiple-parameter communications adapter.

FIG. 3 illustrates a communications adapter 300 having a sensor module 400 and a monitor module 500. The communications adapter 300 communicates patient data derived from a sensor 310 between the sensor module 400, which is located proximate a patient 20 and the monitor module 500, which is located proximate a monitor 360. A wireless link 340 is provided between the sensor module 400 and the monitor module 500, replacing the conventional patient cable, such as a pulse oximetry patient cable 140 (FIG. 1). Advantageously, the sensor module 400 is plug-compatible with a conventional sensor 310. In particular, the sensor connector 318 connects to the sensor module 400 in a similar manner as to a patient cable. Further, the sensor module 400 outputs a drive signal to the sensor 310 and inputs a sensor signal from the sensor 310 in an equivalent manner as a conventional monitor 360. The sensor module 400 may be battery powered or externally powered. External power may be for recharging internal batteries or for powering the sensor module during operation or both.

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As shown in FIG. 3, the monitor module 500 is advantageously plug-compatible with a conventional monitor 360. In particular, the monitor's sensor port 362 connects to the monitor module 500 in a similar manner as to a patient cable, such as a pulse oximetry patient cable 140 (FIG. 1). Further, 5 the monitor module 500 inputs a drive signal from the monitor 360 and outputs a corresponding sensor signal to the monitor 360 in an equivalent manner as a conventional sensor 310. As such, the combination sensor module 400 and monitor module 500 provide a plug-compatible wireless replacement for a patient cable, adapting an existing wired physiological measurement system into a wireless physiological measurement system. The monitor module 500 may be battery powered, powered from the monitor, such as by tapping current from a monitor's LED drive, or externally 15 powered from an independent AC or DC power source.

Although a communications adapter 300 is described herein with respect to a pulse oximetry sensor and monitor, one of ordinary skill in the art will recognize that a communications adapter may provide a plug-compatible wireless replace for a patient cable that connects any physiological sensor and corresponding monitor. For example, a communications adapter 300 may be applied to a biopotential sensor, a non-invasive blood pressure (NIBP) sensor, a respiratory rate sensor, a glucose sensor and the corresponding monitors, to name a few.

Sensor Module Physical Configurations

FIGS. 4A-B illustrate physical embodiments of a sensor module 400. FIG. 4A illustrates a wrist-mounted module 410 having a wrist strap 411, a case 412 and an auxiliary 30 cable 420. The case 412 contains the sensor module electronics, which are functionally described with respect to FIG. 6, below. The case 412 is mounted to the wrist strap 411, which attaches the wrist-mounted module 410 to a patient 20. The auxiliary cable 420 mates to a sensor 35 connector 318 and a module connector 414, providing a wired link between a conventional sensor 310 and the wrist-mounted module 410. Alternatively, the auxiliary cable 420 is directly wired to the sensor module 400. The wrist-mounted module 410 may have a display 415 that 40 shows sensor measurements, module status and other visual indicators, such as monitor status. The wrist-mounted module 410 may also have keys (not shown) or other input mechanisms to control its operational mode and characteristics. In an alternative embodiment, the sensor 310 may 45 have a tail (not shown) that connects directly to the wristmounted module 410, eliminating the auxiliary cable 420.

FIG. 4B illustrates a clip-on module 460 having a clip 461, a case 462 and an auxiliary cable 470. The clip 461 attaches the clip-on module 460 to patient clothing or 50 objects near a patient 20, such as a bed frame. The auxiliary cable 470 mates to the sensor connector 318 and functions as for the auxiliary cable 420 (FIG. 4A) of the wrist-mounted module 410 (FIG. 4A), described above. The clip-on module 460 may have a display 463 and keys 464 as 55 for the wrist-mounted module 410 (FIG. 4A). Either the wrist-mounted module 410 or the clip-on module 460 may have other input or output ports (not shown) that download software, configure the module, or provide a wired connection to other measurement instruments or computing 60 devices, to name a few examples.

Monitor Module Physical Configurations

FIGS. 5A-C illustrate physical embodiments of a monitor module 500. FIG. 5A illustrates a direct-connect module 510 having a case 512 and an integrated monitor connector 514. 65 The case 512 contains the monitor module electronics, which are functionally described with respect to FIG. 7,

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below. The monitor connector **514** mimics that of the monitor end of a patient cable, such as a pulse oximetry patient cable **140** (FIG. 1), and electrically and mechanically connects the monitor module **510** to the monitor **360** via the monitor's sensor port **362**.

FIG. 5B illustrates a cable-connect module 540 having a case 542 and an auxiliary cable 550. The case 542 functions as for the direct-connect module 510 (FIG. 5A), described above. Instead of directly plugging into the monitor 360, the cable-connect module 540 utilizes the auxiliary cable 550, which mimics the monitor end of a patient cable, such as a pulse oximetry patient cable 140 (FIG. 1), and electrically connects the cable-connect module 540 to the monitor sensor port 362.

FIG. 5C illustrates a plug-in module 570 having a plug-in case 572 and an auxiliary cable 580. The plug-in case 572 is mechanically compatible with the plug-in chassis of a multiparameter monitor 370 and may or may not electrically connect to the chassis backplane. The auxiliary cable 580 mimics a patient cable and electrically connects the plug-in module 570 to the sensor port 372 of another plug-in device. A direct-connect module 510 (FIG. 5A) or a cable-connect module 540 (FIG. 5B) may also be used with a multiparameter monitor 370.

In a multiparameter embodiment, such as described with respect to FIGS. 13-14, below, a monitor module 500 may connect to multiple plug-in devices of a multiparameter monitor 370. For example, a cable-connect module 540 (FIG. 5B) may have multiple auxiliary cables 550 (FIG. 5B) that connect to multiple plug-in devices installed within a multiparameter monitor chassis. Similarly, a plug-in module 570 may have one or more auxiliary cables 580 with multiple connectors for attaching to the sensor ports 372 of multiple plug-in devices.

Communications Adapter Functions

FIGS. 6-7 illustrate functional embodiments of a communications adapter. FIG. 6 illustrates a sensor module 400 having a sensor interface 610, a signal processor 630, an encoder 640, a transmitter 650 and a transmitting antenna 670. A physiological sensor 310 provides an input sensor signal 612 at the sensor connector 318. Depending on the sensor 310, the sensor module 400 may provide one or more drive signals 618 to the sensor 310. The sensor interface 610 inputs the sensor signal 612 and outputs a conditioned signal 614. The conditioned signal 614 may be coupled to the transmitter 650 or further processed by a signal processor 630. If the sensor module configuration utilizes a signal processor 630, it derives a parameter signal 632 responsive to the sensor signal 612, which is then coupled to the transmitter 650. Regardless, the transmitter 650 inputs a baseband signal 642 that is responsive to the sensor signal **612**. The transmitter **650** modulates the baseband signal **642** with a carrier to generate a transmit signal 654. The transmit signal 654 may be derived by various amplitude, frequency or phase modulation schemes, as is well known in the art. The transmit signal 654 is coupled to the transmit antenna 670, which provides wireless communications to a corresponding receive antenna 770 (FIG. 7), as described below.

As shown in FIG. 6, the sensor interface 610 conditions and digitizes the sensor signal 612 to generate the conditioned signal 614. Sensor signal conditioning may be performed in the analog domain or digital domain or both and may include amplification and filtering in the analog domain and filtering, buffering and data rate modification in the digital domain, to name a few. The resulting conditioned signal 614 is responsive to the sensor signal 612 and may be used to calculate or derive a parameter signal 632.

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Further shown in FIG. 6, the signal processor 630 performs signal processing on the conditioned signal 614 to generate the parameter signal 632. The signal processing may include buffering, digital filtering, smoothing, averaging, adaptive filtering and frequency transforms to name a 5 few. The resulting parameter signal 632 may be a measurement calculated or derived from the conditioned signal, such as oxygen saturation, pulse rate, blood glucose, blood pressure and EKG to name a few. Also, the parameter signal 632 may be an intermediate result from which the above-stated 10 measurements may be calculated or derived.

As described above, the sensor interface 610 performs mixed analog and digital pre-processing of an analog sensor signal and provides a digital output signal to the signal processor 630. The signal processor 630 then performs 15 digital post-processing of the front-end processor output. In alternative embodiments, the input sensor signal 612 and the output conditioned signal 614 may be either analog or digital, the front-end processing may be purely analog or purely digital, and the back-end processing may be purely 20 analog or mixed analog or digital.

In addition, FIG. 6 shows an encoder 640, which translates a digital word or serial bit stream, for example, into the baseband signal 642, as is well-known in the art. The baseband signal 642 comprises the symbol stream that 25 drives the transmit signal 654 modulation, and may be a single signal or multiple related signal components, such as in-phase and quadrature signals. The encoder 640 may include data compression and redundancy, also well-known in the art.

FIG. 7 illustrates a monitor module 500 having a receive antenna 770, a receiver 710, a decoder 720, a waveform processor 730 and a monitor interface 750. A receive signal 712 is coupled from the receive antenna 770, which provides wireless communications to a corresponding transmit 35 antenna 670 (FIG. 6), as described above. The receiver 710 inputs the receive signal 712, which corresponds to the transmit signal 654 (FIG. 6). The receiver 710 demodulates the receive signal to generate a baseband signal 714. The decoder 720 translates the symbols of the demodulated 40 baseband signal 714 into a decoded signal 724, such as a digital word stream or bit stream. The waveform processor 730 inputs the decoded signal 724 and generates a constructed signal 732. The monitor interface 750 is configured to communicate the constructed signal 732 to a sensor port 45 362 of a monitor 360. The monitor 360 may output a sensor drive signal 754, which the monitor interface 750 inputs to the waveform processor 730 as a monitor drive signal 734. The waveform processor 730 may utilize the monitor drive signal 734 to generate the constructed signal 732. The 50 monitor interface 750 may also provide characterization information 758 to the waveform processor 730, relating to the monitor 360, the sensor 310 or both, that the waveform processor 730 utilizes to generate the constructed signal 732.

The constructed signal **732** is adapted to the monitor **360** 55 so that measurements derived by the monitor **360** from the constructed signal **732** are generally equivalent to measurements derivable from the sensor signal **612** (FIG. **6**). Note that the sensor **310** (FIG. **6**) may or may not be directly compatible with the monitor **360**. If the sensor **310** (FIG. **6**) 60 is compatible with the monitor **360**, the constructed signal **732** is generated so that measurements derived by the monitor **360** from the constructed signal **732** are generally equivalent (within clinical significance) with those derivable directly from the sensor signal **612** (FIG. **6**). If the sensor 65 **310** (FIG. **6**) is not compatible with the monitor **360**, the constructed signal **732** is generated so that measurements

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derived by the monitor 360 from the constructed signal 732 are generally equivalent to those derivable directly from the sensor signal 612 (FIG. 6) using a compatible monitor. Wireless Pulse Oximetry

FIGS. **8-11** illustrate pulse oximeter embodiments of a communications adapter. FIGS. **8-9** illustrate a sensor module and a monitor module, respectively, configured to communicate measured pulse oximeter parameters. FIG. **10-11** illustrate a sensor module and a monitor module, respectively, configured to communicate a plethysmograph signal. Parameter Transmission

FIG. 8 illustrates a pulse oximetry sensor module 800 having a sensor interface 810, signal processor 830, encoder 840, transmitter 850, transmitting antenna 870 and controller 890. The sensor interface 810, signal processor 830 and controller 890 function as described with respect to FIG. 2, above. The sensor interface 810 communicates with a standard pulse oximetry sensor 310, providing an LED drive signal 818 to the LED emitters 312 and receiving a sensor signal 812 from the detector 314 in response. The sensor interface 810 provides front-end processing of the sensor signal 812, also described above, providing a plethysmograph signal 814 to the signal processor 830. The signal processor 830 then derives a parameter signal 832 that comprises a real time measurement of oxygen saturation and pulse rate. The parameter signal 832 may include other parameters, such as measurements of perfusion index and signal quality. In one embodiment, the signal processor is an MS-5 or MS-7 board available from Masimo Corporation, Irvine. Calif.

As shown in FIG. 8, the encoder 840, the transmitter 850 and the transmitting antenna 870 function as described with respect to FIG. 6, above. For example, the parameter signal 832 may be a digital word stream that is serialized into a bit stream and encoded into a baseband signal 842. The baseband signal 842 may be, for example, two bit symbols that drive a quadrature phase shift keyed (QPSK) modulator in the transmitter 850. Other encodings and modulations are also applicable, as described above. The transmitter 850 inputs the baseband signal 842 and generates a transmit signal 854 that is a modulated carrier having a frequency suitable for short-range transmission, such as within a hospital room, doctor's office, emergency vehicle or critical care ward, to name a few. The transmit signal 854 is coupled to the transmit antenna 870, which provides wireless communications to a corresponding receive antenna 970 (FIG. 9), as described below.

FIG. 9 illustrates a monitor module 900 having a receive antenna 970, a receiver 910, a decoder 920, a waveform generator 930 and an interface cable 950. The receive antenna 970, receiver 910 and decoder 920 function as described with respect to FIG. 7, above. In particular, the receive signal 912 is coupled from the receive antenna 970, which provides wireless communications to a corresponding transmit antenna 870 (FIG. 8). The receiver 910 inputs the receive signal 912, which corresponds to the transmit signal 854 (FIG. 8). The receiver 810 demodulates the receive signal 912 to generate a baseband signal 914. Not accounting for transmission errors, the baseband signal 914 corresponds to the sensor module baseband signal 842 (FIG. 8), for example a symbol stream of two bits each. The decoder 920 assembles the baseband signal 914 into a parameter signal 924, which, for example, may be a sequence of digital words corresponding to oxygen saturation and pulse rate.

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Again, not accounting for transmission errors, the monitor module parameter signal 924 corresponds to the sensor module parameter signal 832 (FIG. 8), derived by the signal processor 830 (FIG. 8).

Also shown in FIG. 9, the waveform generator 930 is a 5 particular embodiment of the waveform processor 730 (FIG. 7) described above. The waveform generator 930 generates a synthesized waveform 932 that the pulse oximeter monitor 360 can process to calculate SpO₂ and pulse rate values or exception messages. In the present embodiment, the waveform generator output does not reflect a physiological waveform. In particular, the synthesized waveform is not physiological data from the sensor module 800, but is a waveform synthesized from predetermined stored waveform data to cause the monitor 360 to calculate oxygen saturation and 15 pulse rate equivalent to or generally equivalent (within clinical significance) to that calculated by the signal processor 830 (FIG. 8). The actual intensity signal from the patient received by the detector 314 (FIG. 8) is not provided to the monitor 360 in the present embodiment. Indeed, the wave- 20 form provided to the monitor 360 will usually not resemble a plethysmographic waveform or other physiological data from the patient to whom the sensor module 800 (FIG. 8) is attached.

The synthesized waveform 932 is modulated according to 25 the drive signal input 934. That is, the pulse oximeter monitor 360 expects to receive a red and IR modulated intensity signal originating from a detector, as described with respect to FIGS. 1-2, above. The waveform generator 930 generates the synthesized waveform 932 with a predetermined shape, such as a triangular or sawtooth waveform stored in waveform generator memory or derived by a waveform generator algorithm. The waveform is modulated synchronously with the drive input 934 with first and second amplitudes that are processed in the monitor 360 as red and 35 IR portions of a sensor signal. The frequency and the first and second amplitudes are adjusted so that pulse rate and oxygen saturation measurements derived by the pulse oximeter monitor 360 are generally equivalent to the parameter measurements derived by the signal processor 830 (FIG. 8), 40 as described above. One embodiment of a waveform generator 930 is described in U.S. Patent Application No. 60/117,097 entitled "Universal/Upgrading Pulse Oximeter," assigned to Masimo Corporation, Irvine, Calif. and incorporated by reference herein. Although the waveform gen- 45 erator 930 is described above as synthesizing a waveform that does not resemble a physiological signal, one of ordinary skill will recognize that another embodiment of the waveform generator 930 could incorporate, for example, a plethysmograph simulator or other physiological signal 50 simulator.

Further shown in FIG. 9, the interface cable 950 functions in a manner similar to the monitor interface 750 (FIG. 7) described above. The interface cable 950 is configured to communicate the synthesized waveform 932 to the monitor 55 360 sensor port and to communicate the sensor drive signal 934 to the waveform generator 930. The interface cable 950 may include a ROM 960 that contains monitor and sensor characterization data. The ROM 960 is read by the waveform generator 930 so that the synthesized waveform 932 is 60 adapted to a particular monitor 360. For example, the ROM 960 may contain calibration data of red/IR versus oxygen saturation, waveform amplitude and waveform shape information. An interface cable is described in U.S. Patent Application No. 60/117,092, referenced above. Monitor- 65 specific SatShareTM brand interface cables are available from Masimo Corporation, Irvine, Calif. In an alternative

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embodiment, such as a direct connect monitor module as illustrated in FIG. 5A, an interface cable 950 is not used and the ROM 960 may be incorporated within the monitor module 900 itself.

Plethysmograph Transmission

FIG. 10 illustrates another pulse oximetry sensor module 1000 having a sensor interface 1010, encoder 1040, transmitter 1050, transmitting antenna 1070 and controller 1090, which have the corresponding functions as those described with respect to FIG. 8, above. The encoder 1040, however, inputs a plethysmograph signal 1014 rather than oxygen saturation and pulse rate measurements 832 (FIG. 8). Thus, the sensor module 1000 according to this embodiment encodes and transmits a plethysmograph signal 1014 to a corresponding monitor module 1100 (FIG. 11) in contrast to derived physiological parameters, such as oxygen saturation and pulse rate. The plethysmograph signal 1014 is illustrated in FIG. 10 as being a direct output from the sensor interface 1010. In another embodiment, the sensor module 1000 incorporates a decimation processor, not shown, after the sensor interface 1010 so as to provide a plethysmograph signal 1014 having a reduced sample rate.

FIG. 11 illustrates another pulse oximetry monitor module 1100 having a receive antenna 1170, a receiver 1110, a decoder 1120 and an interface cable 1150, which have the corresponding functions as those described with respect to FIG. 9, above. This monitor module embodiment 1100, however, has a waveform modulator 1200 rather than a waveform generator 930 (FIG. 9), as described above. The waveform modulator 1200 inputs a plethysmograph signal from the decoder 1120 rather than oxygen saturation and pulse rate measurements, as described with respect to FIG. 9, above. Further, the waveform modulator 1200 provides an modulated waveform 1132 to the pulse oximeter monitor 360 rather than a synthesized waveform, as described with respect to FIG. 9. The modulated waveform 1132 is a plethysmographic waveform modulated according to the monitor drive signal input 1134. That is, the waveform modulator 1200 does not synthesize a waveform, but rather modifies the received plethysmograph signal 1124 to cause the monitor 360 to calculate oxygen saturation and pulse rate generally equivalent (within clinical significance) to that derivable by a compatible, calibrated pulse oximeter directly from the sensor signal 1012 (FIG. 10). The waveform modulator 1200 is described in further detail with respect to FIG. 12, below.

FIG. 12 shows a waveform modulator 1200 having a demodulator 1210, a red digital-to-analog converter (DAC) 1220, an IR DAC 1230, a red amplifier 1240, an IR amplifier 1250, a modulator 1260, a modulator control 1270, a look-up table (LUT) 1280 and a ratio calculator 1290. The waveform modulator 1200 demodulates red and IR plethysmographs ("pleths") from the decoder output 1124 into a separate red pleth 1222 and IR pleth 1232. The waveform modulator 1200 also adjusts the amplitudes of the pleths 1222, 1232 according to stored calibration curves for the sensor 310 (FIG. 10) and the monitor 360 (FIG. 11). Further, the waveform modulator 1200 re-modulates the adjusted red pleth 1242 and adjusted IR pleth 1252, generating a modulated waveform 1132 to the monitor 360 (FIG. 11).

As shown in FIG. 12, the demodulator 1210 performs the demodulation function described above, generating digital red and IR pleth signals 1212, 1214. The DACs 1220, 1230 convert the digital pleth signals 1212, 1214 to corresponding analog pleth signals 1222, 1232. The amplifiers 1240, 1250 have variable gain control inputs 1262, 1264 and perform the amplitude adjustment function described above, gener-

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ating adjusted red and IR pleth signals 1242, 1252. The modulator 1260 performs the re-modulation function described above, combining the adjusted red and IR pleth signals 1242, 1252 according to a control signal 1272. The modulator control 1270 generates the control signal 1272 synchronously with the LED drive signal(s) 1134 from the monitor 360.

Also shown in FIG. 12, the ratio calculator 1290 derives a red/IR ratio from the demodulator outputs 1212, 1214. The LUT 1280 stores empirical calibration data for the sensor 10 310 (FIG. 10). The LUT 1280 also downloads monitor-specific calibration data from the ROM 1160 (FIG. 11) via the ROM output 1158. From this calibration data, the LUT 1280 determines a desired red/IR ratio for the modulated waveform 1132 and generates red and IR gain outputs 1262, 15 1264 to the corresponding amplifiers 1240, 1250, accordingly. A desired red/IR ratio is one that allows the monitor 360 (FIG. 11) to derive oxygen saturation measurements from the modulated waveform 1132 that are generally equivalent to that derivable directly from the sensor signal 20 1012 (FIG. 10).

One of ordinary skill in the art will recognize that some of the signal processing functions described with respect to FIGS. **8-11** may be performed either within a sensor module or within a monitor module. Signal processing functions 25 performed within a sensor module may advantageously reduce the transmission bandwidth to a monitor module at a cost of increased sensor module size and power consumption. Likewise, signal processing functions performed within a monitor module may reduce sensor module size and 30 power consumption at a cost of increase transmission bandwidth.

For example, a monitor module embodiment 900 (FIG. 9) described above receives measured pulse oximeter parameters, such as oxygen saturation and pulse rate, and gener- 35 ates a corresponding synthesized waveform. In that embodiment, the oxygen saturation and pulse rate computations are performed within a sensor module 800 (FIG. 8). Another monitor module embodiment 1100 (FIG. 11), also described above, receives a plethysmograph waveform and generates 40 a remodulated waveform. In that embodiment, minimal signal processing is performed within a sensor module 1000(FIG. 10). In yet another embodiment, not shown, a sensor module transmits a plethysmograph waveform or a decimated plethysmograph waveform having a reduced sample 45 rate. A corresponding monitor module has a signal processor, such as described with respect to FIG. 8, in addition to a waveform generator, as described with respect to FIG. 9. The signal processor computes pulse oximeter parameters and the waveform generator generates a corresponding 50 synthesized waveform, as described above. In this embodiment, minimal signal processing is performed within the sensor module, and the monitor module functions are performed on the pulse oximeter parameters computed within the monitor module.

Wireless Multiple Parameter Measurements

FIGS. 13-14 illustrate a multiple parameter communications adapter. FIG. 13 illustrates a multiple parameter sensor module 1300 having sensor interfaces 1310, one or more signal processors 1330, a multiplexer and encoder 1340, a 60 transmitter 1350, a transmitting antenna 1370 and a controller 1390. One or more physiological sensors 1301 provide input sensor signals 1312 to the sensor module 1300. Depending on the particular sensors 1301, the sensor module 1300 may provide one or more drive signals 1312 to the 65 sensors 1301 as determined by the controller 1390. The sensor interfaces 1310 input the sensor signals 1312 and

output one or more conditioned signals 1314. The conditioned signals 1314 may be coupled to the transmitter 1350 or further processed by the signal processors 1330. If the sensor module configuration utilizes signal processors 1330, it derives multiple parameter signals 1332 responsive to the sensor signals 1312, which are then coupled to the transmitter 1350. Regardless, the transmitter 1350 inputs a baseband signal 1342 that is responsive to the sensor signals 1312. The transmitter 1350 modulates the baseband signal 1342 with a carrier to generate a transmit signal 1354, which is coupled to the transmit antenna 1370 and communicated to a corresponding receive antenna 1470 (FIG. 14), as described with respect to FIG. 6, above. Alternatively, there may be multiple baseband signals 1342, and the transmitter 1350 may transmit on multiple frequency channels, where each channel coveys data responsive to one or more of the sensor signals 1314.

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As shown in FIG. 13, the sensor interface 1310 conditions and digitizes the sensor signals 1312 as described for a single sensor with respect to FIG. 6, above. The resulting conditioned signals 1314 are responsive to the sensor signals 1312. The signal processors 1330 perform signal processing on the conditioned signals 1314 to derive parameter signals 1332, as described for a single conditioned signal with respect to FIG. 6, above. The parameter signals 1332 may be physiological measurements such as oxygen saturation, pulse rate, blood glucose, blood pressure, EKG, respiration rate and body temperature to name a few, or may be intermediate results from which the above-stated measurements may be calculated or derived. The multiplexer and encoder 1340 combines multiple digital word or serial bit streams into a single digital word or bit stream. The multiplexer and encoder also encodes the digital word or bit stream to generate the baseband signal 1342, as described with respect to FIG. 6, above.

FIG. 14 illustrates a multiple parameter monitor module 1400 having a receive antenna 1470, a receiver 1410, a demultiplexer and decoder 1420, one or more waveform processors 1430 and a monitor interface 1450. The receiver 1410 inputs and demodulates the receive signal 1412 corresponding to the transmit signal 1354 (FIG. 13) to generate a baseband signal 1414 as described with respect to FIG. 7, above. The demultiplexer and decoder 1420 separates the symbol streams corresponding to the multiple conditioned signals 1314 (FIG. 13) and/or parameter signals 1332 (FIG. 13) and translates these symbol streams into multiple decoded signals 1422, as described for a single symbol stream with respect to FIG. 7, above. Alternatively, multiple frequency channels are received to generate multiple baseband signals, each of which are decoded to yield multiple decoded signals 1422. The waveform processors 1430 input the decoded signals 1422 and generate multiple constructed signals 1432, as described for a single decoded signal with respect to FIGS. 7-12, above. The monitor interface 1450 is configured to communicate the constructed signals 1432 to the sensor ports of a multiple parameter monitor 1401 or multiple single parameter monitors, in a manner similar to that for a single constructed signal, as described with respect to FIGS. 7-12, above. In particular, the constructed signals 1432 are adapted to the monitor 1401 so that measurements derived by the monitor 1401 from the constructed signals 1432 are generally equivalent to measurements derivable directly from the sensor signals 1312 (FIG. 13).

A physiological measurement communications adapter is described above with respect to wireless communications and, in particular, radio frequency communications. A sensor module and monitor module, however, may also communi-

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cate via wired communications, such as telephone, Internet or fiberoptic cable to name a few. Further, wireless communications can also utilize light frequencies, such as IR or laser to name a few.

A physiological measurement communications adapter 5 has been disclosed in detail in connection with various embodiments. These embodiments are disclosed by way of examples only. One of ordinary skill in the art will appreciate many variations and modifications of a physiological measurement communications adapter within the scope of 10 the claims that follow.

What is claimed is:

- 1. A body worn mobile medical monitoring device configured to minimize cable wiring from a sensor by placement 15 of one or more sensor communication ports, the mobile medical monitoring device comprising:
 - a housing configured to be secured on a lower arm of a patient being monitored via a strap extending around the lower arm of the patient;
 - a display positioned on a face of the housing, opposite the strap, so as to be visible to a user;
 - a first sensor communication port positioned on a side of the housing and configured to face a hand of the lower arm of the patient when the mobile medical monitoring 25 device is mounted to the lower arm of the patient, wherein:
 - the side of the housing faces the hand of the lower arm of the patient of the patient when the mobile medical monitoring device is mounted to the lower arm of the patient,
 - the first sensor communication port is configured to provide wired communication with a pulse oximetry sensor attached to a digit of the hand of the patient,
 - the wired communication with the pulse oximetry 35 sensor provided at least partly in the analog domain, and
 - the first sensor communication port is positioned on the side of the housing such that a path from the first sensor communication port on the side of the housing to the digit of the patient is substantially perpendicular to the side of the housing and shorter than any other path from any other side of the housing to the digit of the patient;
 - a plurality of additional sensor communications ports 45 positioned on the housing and configured to provide wired communication with a plurality of additional physiological sensors at least partly in the digital domain; and
 - one or more processors and a transmitter configured to: 50 display, on the display, physiological measurements derived from the pulse oximetry sensor and the plurality of additional physiological sensors; and
 - wirelessly transmit information indicative of the physiological measurements to a remote computing 55 device.
- 2. The mobile medical monitoring device of claim 1, wherein the wired communication with the pulse oximetry sensor is provided via a tail extending from the pulse oximetry sensor.
- 3. The mobile medical monitoring device of claim 2, wherein the tail comprises a cable that is configured to be removably attachable to the first sensor communication port.
- **4**. The mobile medical monitoring device of claim **3**, wherein a length of the cable corresponds to the path from 65 the sensor communication port on the side of the housing to the digit of the patient.

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- 5. The mobile medical monitoring device of claim 3, wherein the cable is appropriately sized based on the path from the sensor communication port on the side of the housing to the digit of the patient.
- **6.** The mobile medical monitoring device of claim **3**, wherein the path from the sensor communication port on the side of the housing to the digit of the patient runs at least partly along a backside of the hand of the patient.
- 7. The mobile medical monitoring device of claim 1, wherein the face of the housing comprises a single user interface.
- **8**. The mobile medical monitoring device of claim **7**, wherein the single user interface comprises the display.
- 9. The mobile medical monitoring device of claim 8, wherein:
 - the housing comprises a back side that is opposite the face of the housing.
- the strap is mountable to the back side of the housing, and the face of the housing is raised from the strap and the lower arm of the patient to enable positioning of the first sensor communication port on the side of the housing between the lower arm of the patient and the face of the housing.
- 10. The mobile medical monitoring device of claim 9, wherein:
 - the front side of the housing comprises a bezel and the display, and
 - a top of the first sensor communication port is located below the face of the housing.
- 11. The mobile medical monitoring device of claim 10, wherein the display is positioned centrally on the face of the housing.
- 12. The mobile medical monitoring device of claim 11, wherein the display positioned on the face of the housing is sized such that the display covers most of a length of a shortest dimension of the face of the housing.
- 13. A body worn, battery-powered medical monitoring device configured to provide on-patient and remote monitoring of patient physiological parameters, the medical monitoring device comprising:
 - a battery configured to provide power to the medical monitoring device such that the medical monitoring device may operate without a wired power connection;
 - a case configured to house the battery; a strap configured to attach the case to an arm of a patient and be mountable to the case:
 - a first communications port positioned on a face of a side of the case configured to be nearest to a hand of the arm of the patient when the case is mounted to the arm of the patient, the first communications port configured to removably couple with a cable of a finger- or thumbtype pulse oximetry sensor and positioned on the face of the side of the case to provide a path from the first communications port to a digit of the hand of the patient that avoids tangling of the cable, the first communications port configured such that the cable perpendicularly extends from the face of the side of the case when the cable is coupled to the first communications port;
 - a second communications port configured to provide wired communications with a second physiological sensor arrangement at least partly via digital communications:
 - a third communications port configured to provide wired communications with a third physiological sensor arrangement;

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- a display configured to provide real time measurements of patient physiological parameters based at least in part on data obtained from at least the pulse oximetry sensor via the first communications port; and
- a transmitter configured to wirelessly transmit information indicative of real time measurements of patient physiological parameters based at least in part on data obtained from the pulse oximetry sensor via the first communications port.
- 14. The medical monitoring device of claim 13, wherein the path from the first communications port to a digit of the hand is shorter than any path from any communications port located on any other side of the case to the digit of the hand.
- 15. The medical monitoring device of claim 13 further $_{15}$ comprising:
 - one or more hardware processors configured to:
 - process the data obtained from the pulse oximetry sensor; and
 - determine, based at least in part on the data, the real 20 time measurements of patient physiological parameters.
 - 16. The medical monitoring device of claim 15, wherein: the one or more hardware processors are further configured to:
 - receive additional data from at least the second physiological sensor arrangement and the third physiological sensor arrangement;
 - determine, based at least in part on the additional data, real time measurements of additional patient physiological parameters; and
 - cause to be displayed, on the display, the real time measurements of additional patient physiological parameters; and
 - the transmitter is further configured to:
 - wirelessly transmit information indicative of real time measurements of additional patient physiological parameters based at least in part on the additional data
- 17. The medical monitoring device of claim 16, wherein the display is positioned on a front, user-facing side of the case to enable a user to view the real time measurements of patient physiological parameters and the real time measurements of additional patient physiological parameters.
- 18. The medical monitoring device of claim 17, wherein the second physiological sensor arrangement comprises an EKG sensor arrangement and the third physiological sensor arrangement comprises a blood pressure sensor arrangement.
 - 19. The medical monitoring device of claim 18, wherein: the first, second, and third communication ports are communicatively coupled to respective first, second, and third sensor interfaces; and
 - the first, second, and third sensor interfaces are uniquely 55 configured to receive signals from the respective pulse oximetry sensor, EKG sensor arrangement, and blood pressure sensor arrangement.
- **20**. A body worn portable patient monitoring device configured to provide on-patient and remote monitoring of 60 patient physiological parameters, the portable patient monitoring device comprising:
 - a pulse oximetry sensor configured to be wrapped around a digit of a patient, the pulse oximetry sensor including at least:
 - a light emitter configured to emit light into a tissue site of the digit of the patient;

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- a light detector configured output a first signal responsive to at least a portion of the emitted light after attenuation by tissue of the tissue site; and
- a cable extending from the pulse oximetry sensor and configured to electrically convey the first signal;
- a blood pressure sensor configured to output a second signal responsive to at least a blood pressure parameter of the patient;
- an additional sensor arrangement configured to output a third signal responsive to at least one additional physiological parameter of the patient other than blood pressure or oxygen saturation, the at least one additional physiological parameter including at least one of: temperature or respiration rate;
- a housing configured to be secured to a lower arm of the patient, the housing having a size and shape configured to be secured to the lower arm of the patient;
- a strap mountable to the back side of the housing, the strap configured to secure the housing to the lower arm of the patient;
- a display positioned on a front side of the housing that is opposite a back side of the housing, the display configured to show a status of the portable patient monitoring device and one or more parameter measurements so as to be viewable by a user, wherein the display is positioned centrally on the front side of the display and is sized such that the display spans most of a length of a shortest dimension of the front side of the housing, and wherein the front side of the housing comprises a single user interface and a bezel;
- one or more user input mechanisms configured to control an operational mode of the portable patient monitoring device in response to inputs from a user;
- a first sensor port positioned on a face of a first side of the housing, wherein:
 - the face of the first side of the housing is configured to face toward a hand having the digit of the patient under measurement when the housing is secured to the lower arm of the patient,
 - the first sensor port is configured to removably physically couple with the pulse oximetry sensor via the cable and to electrically receive the first signal from the pulse oximetry sensor,
 - the cable is configured to run from the first sensor port, at least part way along a path substantially perpendicular to the face of the first side of the housing, down the arm of the patient, and to the digit of the patient to which the pulse oximetry sensor is configured to be wrapped around,
 - the front side of the housing is raised from the strap and the lower arm of the patient to enable positioning of the first sensor port on the first side of the housing between the lower arm of the patient and the front side of the housing, and
 - a top of the first sensor port is located below the front of the housing;
- a second sensor port positioned on the housing and configured to provide wired electrical communication with the blood pressure sensor arrangement and to electrically receive second signal from the blood pressure sensor arrangement;
- a third sensor port positioned on the housing and configured to provide electrical wired communication with the additional sensor arrangement and to electrically receive the third signal from the additional sensor arrangement;

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- a rechargeable battery positioned within the housing and configured to power the portable patient monitoring device such that the portable patient monitoring device is portable and wearable by the patient;
- one or more signal processing arrangements positioned 5 within the housing and configured to:
 - receive the first signal from the pulse oximetry sensor via one or more sensor interfaces, wherein the first signal is provided at least partly as an analog signal;
 - process the first signal from the pulse oximetry sensor to determine measurements of oxygen saturation and pulse rate;
 - receive the second signal from the blood pressure sensor arrangement via the one or more sensor interfaces, the second signal responsive to at least a 15 blood pressure parameter of the patient;
 - receive the third signal from the additional sensor arrangement via the one or more sensor interfaces, the third signal responsive to the at least one additional physiological parameter of the patient includ-

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- ing at least one of: temperature or respiration rate, wherein the third signal is provided at least partly as a digital signal; and
- cause the measurements of oxygen saturation, pulse rate, blood pressure, and the at least one additional physiological parameter to all be displayed on the display of the portable patient monitoring device; and
- a transmitter positioned within the housing and configured to:
- wirelessly transmit a transmit signal including the information indicating the measurements of oxygen saturation, pulse rate, blood pressure, and the at least one additional physiological parameter to a separate computing device configured to display, on a remote display, the measurements of oxygen saturation, pulse rate, blood pressure, and the at least one additional physiological parameter.

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(54) WEARABLE PORTABLE PATIENT MONITOR

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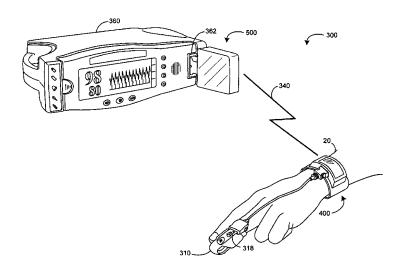
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(57) ABSTRACT

A wearable, portable physiological monitor configured to wirelessly transmit real time information regarding a plurality physiological parameters. The portable monitor includes a plurality of sensor ports, where at least a first sensor port is positioned on a side of a housing of the portable monitor such that, when the portable monitor is attached to an arm of a patient, a wired connection extending from the first sensor port to a first physiological sensor positioned on a digit of the patient follows a path to the digit of the patient that avoids tangling of the wired connection. The portable monitor further includes one or more processing devices configured to cause display of parameter values, combine information indicative of the signals into a single word or bit stream, and encode and generate a baseband signal. Further includes a transmitter to modulate the baseband signal and wirelessly transmit.

20 Claims, 17 Drawing Sheets



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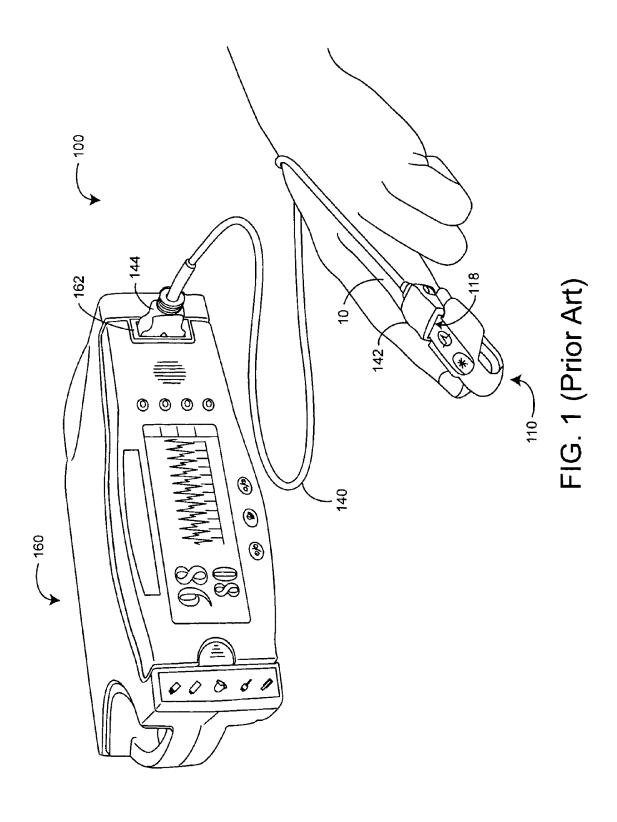
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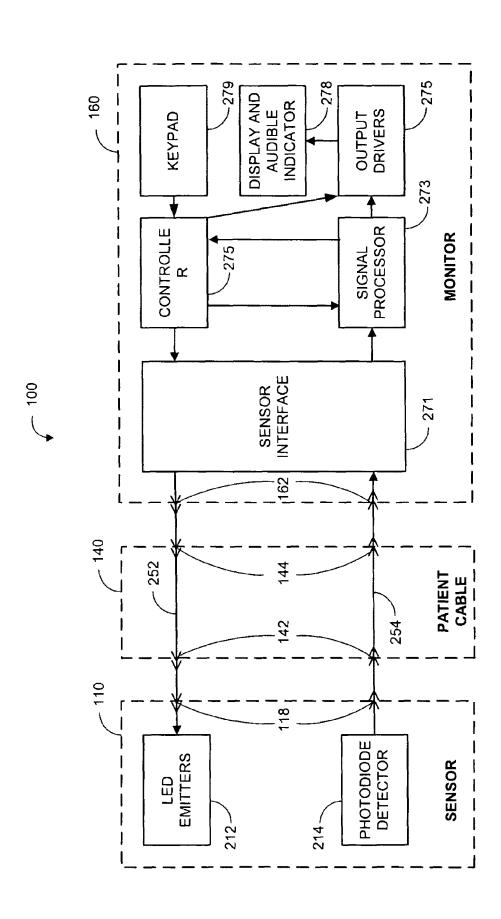
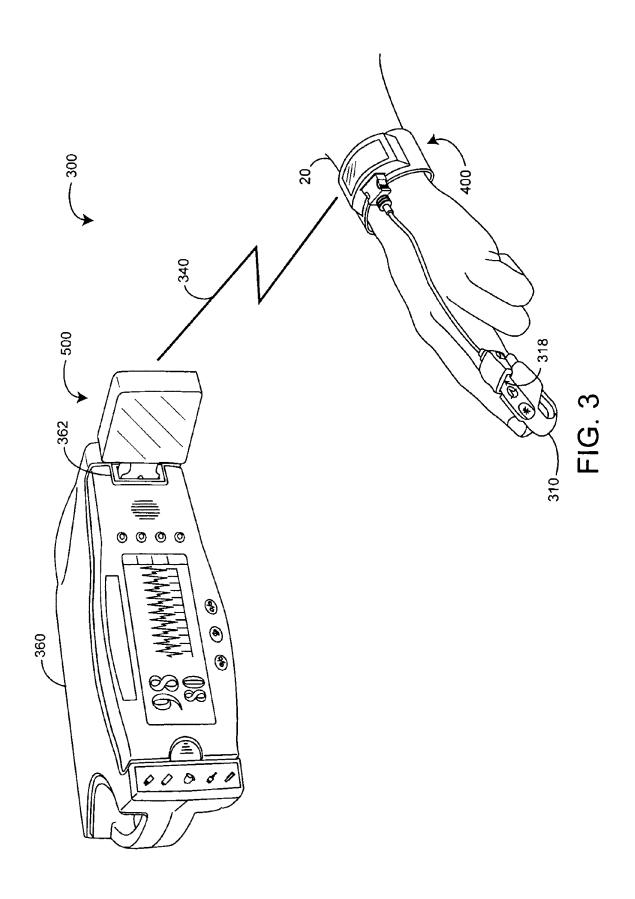


FIG. 2 (Prior Art)

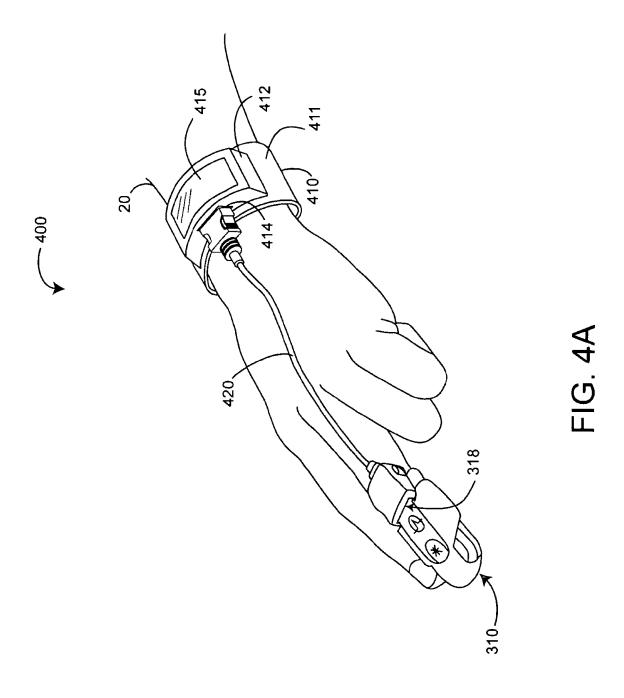
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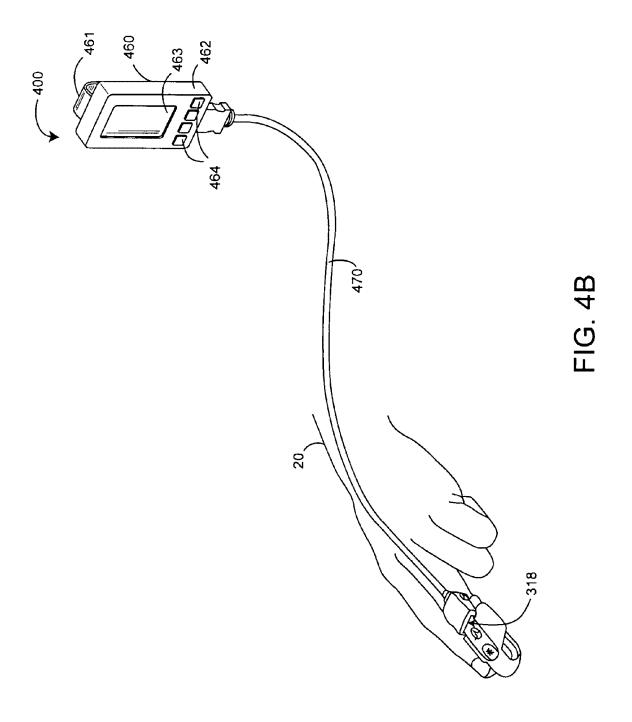
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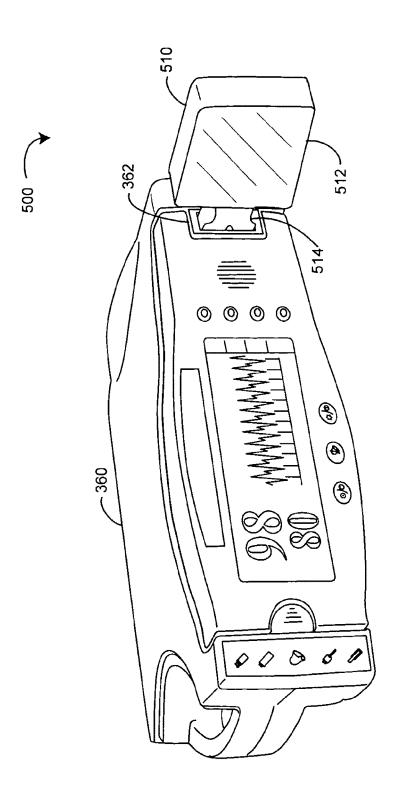


FIG. 54

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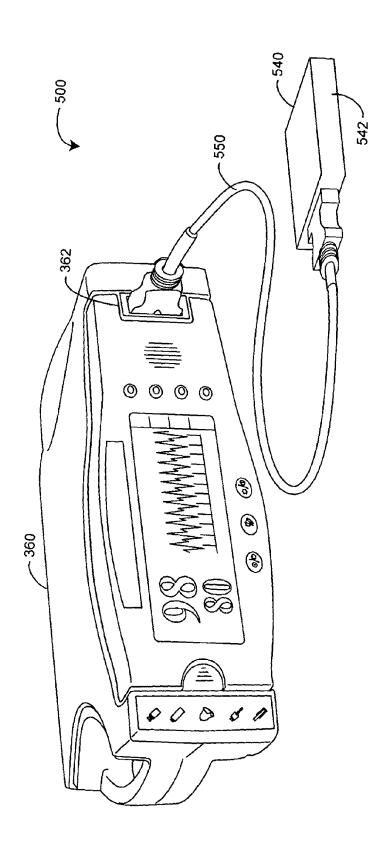
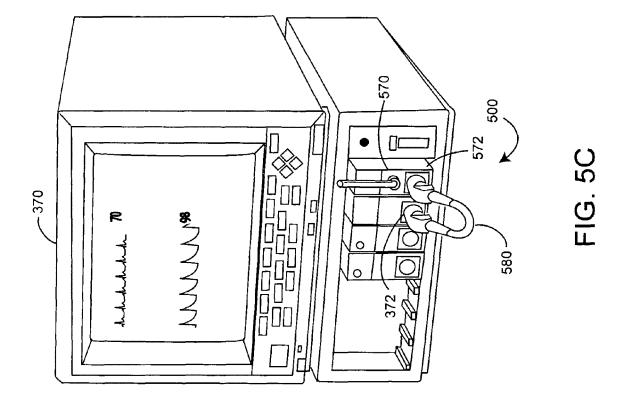


FIG. 5B

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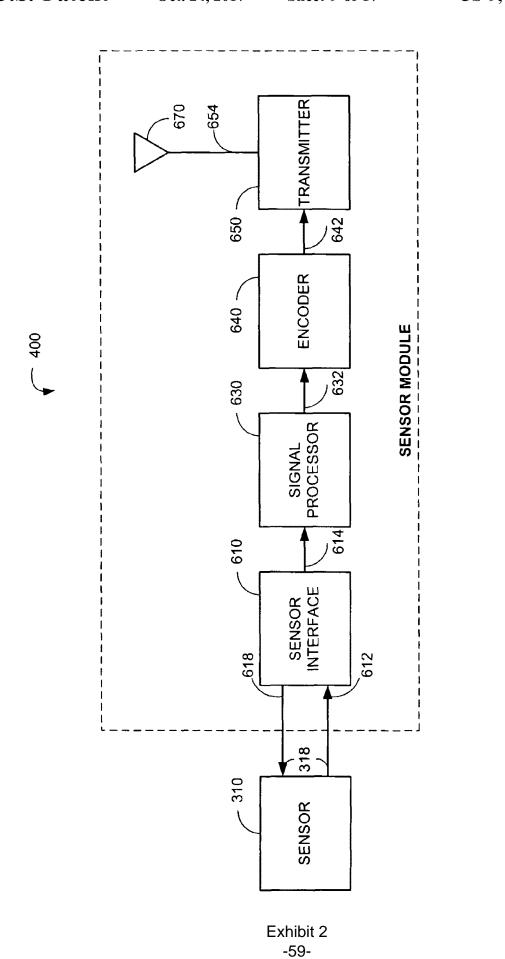


FIG. 6

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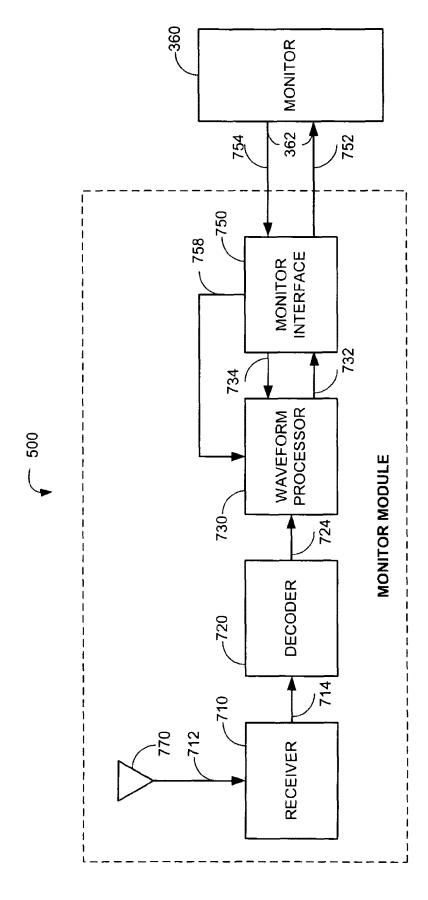


FIG. 7

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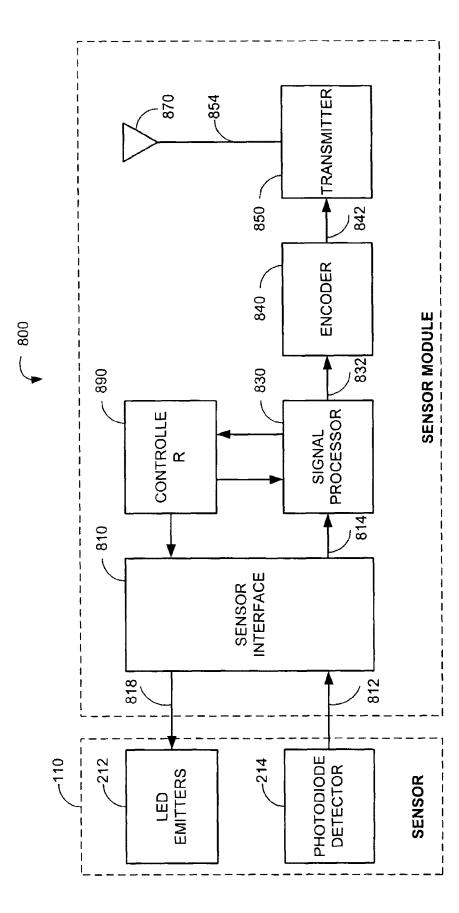


FIG. 8

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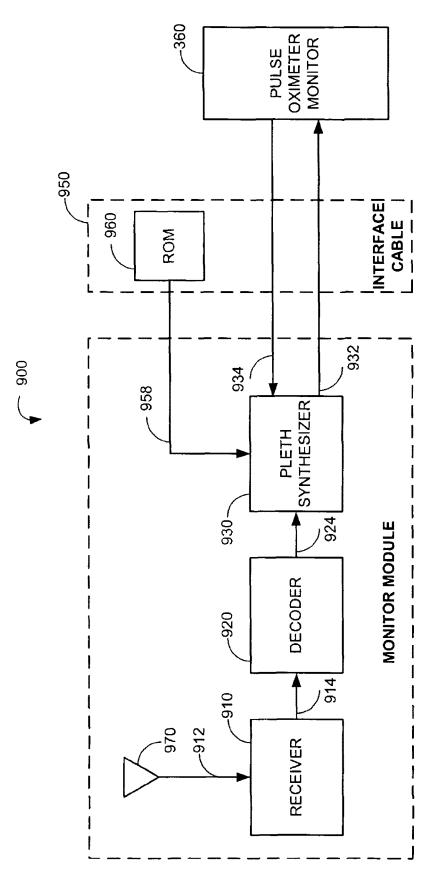


FIG. 9

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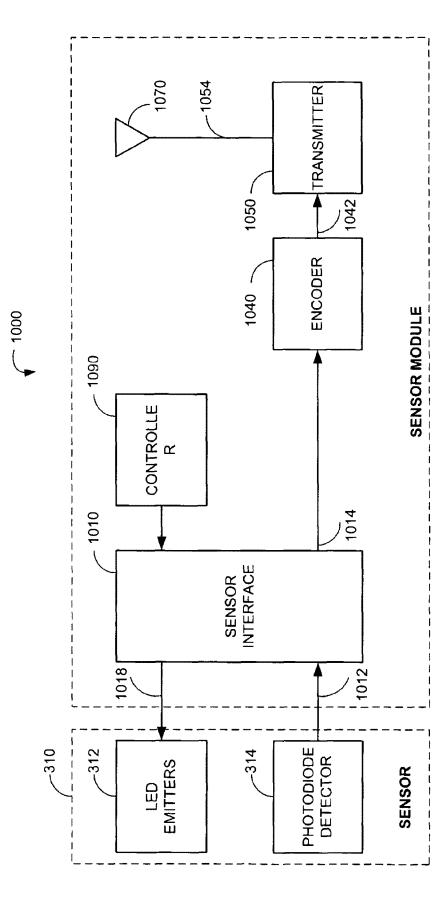


FIG. 10

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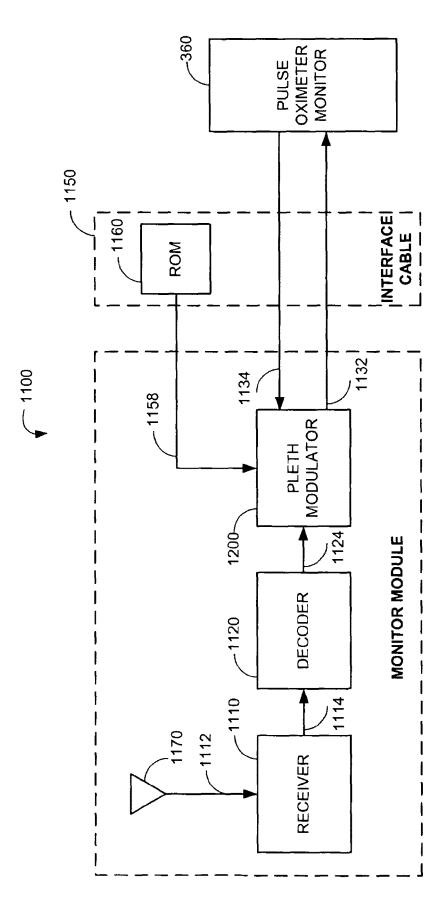
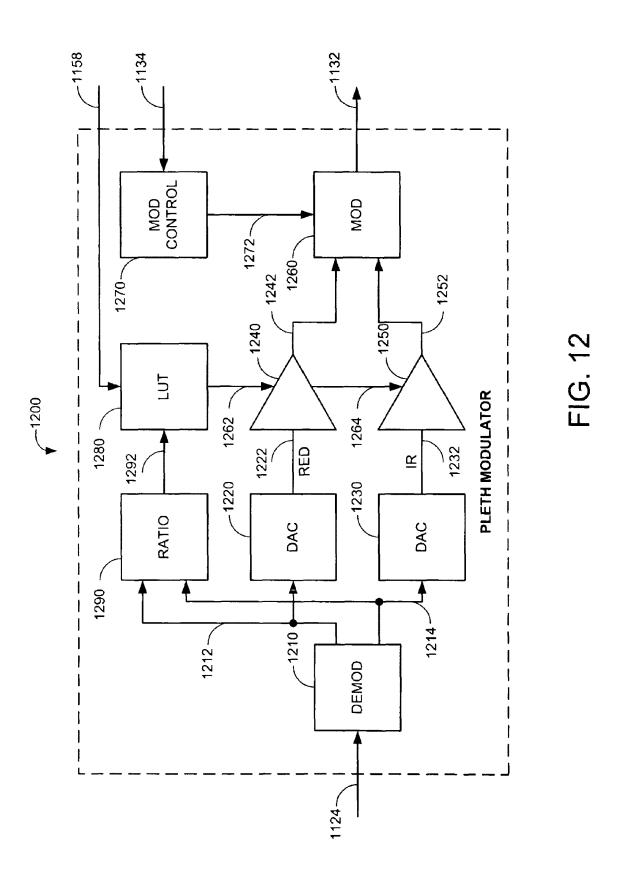


FIG. 11

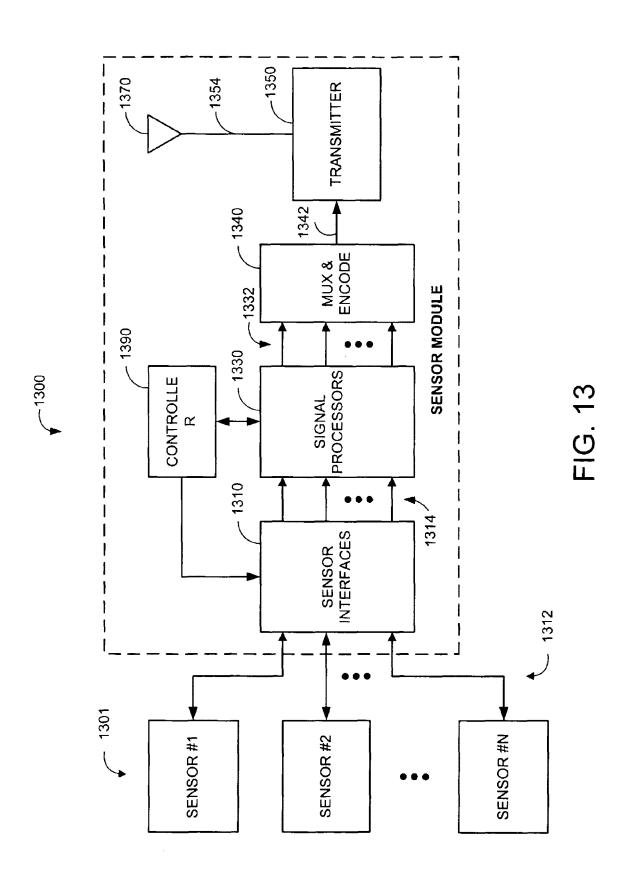
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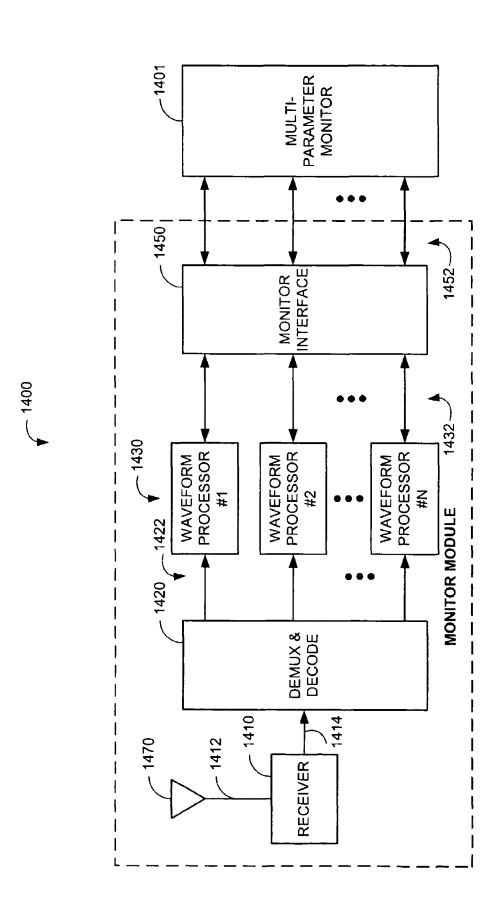


FIG. 14

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WEARABLE PORTABLE PATIENT **MONITOR**

REFERENCE TO RELATED APPLICATION

The present application is a continuation of U.S. patent application Ser. No. 15/448,989, filed on Mar. 3, 2017, entitled "Physiological Measurement Communications Adapter," which is a continuation of U.S. patent application Ser. No. 14/815,232, filed on Jul. 31, 2015, entitled "Physi-10" ological Measurement Communications Adapter," which is a continuation of U.S. patent application Ser. No. 14/217, 788, filed on Mar. 18, 2014, entitled "Wrist-Mounted Physiological Measurement Device," now U.S. Pat. No. 9,113, 832, which is a continuation of U.S. patent application Ser. 15 No. 14/037,137, filed on Sep. 25, 2013, entitled "Physiological Measurement Communications Adapter," now U.S. Pat. No. 9,113,831, which is a continuation of U.S. patent application Ser. No. 12/955,826, filed on Nov. 29, 2010, entitled "Physiological Measurement Communications 20 Adapter," now U.S. Pat. No. 8,548,548, which is a continuation of U.S. patent application Ser. No. 11/417,006, filed on May 3, 2006, entitled "Physiological Measurement Communications Adapter," now U.S. Pat. No. 7,844,315, which claims priority benefit under 35 U.S.C. §120 to, and is a 25 continuation of, U.S. patent application Ser. No. 11/048,330, filed Feb. 1, 2005, entitled "Physiological Measurement Communications Adapter," now U.S. Pat. No. 7,844,314, which is a continuation of U.S. patent application Ser. No. 10/377,933, entitled "Physiological Measurement Commu-30 nications Adapter," now U.S. Pat. No. 6,850,788, which claims priority benefit under 35 U.S.C. §119(e) from U.S. Provisional Application No. 60/367,428, filed Mar. 25, 2002, entitled "Physiological Measurement Communications Adapter." The present application also incorporates the 35 foregoing utility disclosures herein by reference.

BACKGROUND OF THE INVENTION

of blood oxygen, blood pressure, respiratory gas, and EKG among other parameters. Each of these physiological parameters typically requires a sensor in contact with a patient and a cable connecting the sensor to a monitoring device. For example, FIGS. 1-2 illustrate a conventional pulse oximetry 45 system 100 used for the measurement of blood oxygen. As shown in FIG. 1, a pulse oximetry system has a sensor 110. a patient cable 140 and a monitor 160. The sensor 110 is typically attached to a finger 10 as shown. The sensor 110 has a plug 118 that inserts into a patient cable socket 142. 50 The monitor 160 has a socket 162 that accepts a patient cable plug 144. The patient cable 140 transmits an LED drive signal 252 (FIG. 2) from the monitor 160 to the sensor 110 and a resulting detector signal 254 (FIG. 2) from the sensor 110 to the monitor 160. The monitor 160 processes the 55 detector signal 254 (FIG. 2) to provide, typically, a numerical readout of the patient's oxygen saturation, a numerical readout of pulse rate, and an audible indicator or "beep" that occurs in response to each arterial pulse.

As shown in FIG. 2, the sensor 110 has both red and 60 infrared LED emitters 212 and a photodiode detector 214. The monitor 160 has a sensor interface 271, a signal processor 273, a controller 275, output drivers 276, a display and audible indicator 278, and a keypad 279. The monitor 160 determines oxygen saturation by computing the differ- 65 ential absorption by arterial blood of the two wavelengths emitted by the sensor emitters 212, as is well-known in the

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art. The sensor interface 271 provides LED drive current 252 which alternately activates the red and IR LED emitters 212. The photodiode detector 214 generates a signal 254 corresponding to the red and infrared light energy attenuated from transmission through the patient finger 10 (FIG. 1). The sensor interface 271 also has input circuitry for amplification, filtering and digitization of the detector signal 254. The signal processor 273 calculates a ratio of detected red and infrared intensities, and an arterial oxygen saturation value is empirically determined based on that ratio. The controller 275 provides hardware and software interfaces for managing the display and audible indicator 278 and keypad 279. The display and audible indicator 278 shows the computed oxygen status, as described above, and provides the pulse beep as well as alarms indicating oxygen desaturation events. The keypad 279 provides a user interface for setting alarm thresholds, alarm enablement, and display options, to name a few.

SUMMARY OF THE INVENTION

Conventional physiological measurement systems are limited by the patient cable connection between sensor and monitor. A patient must be located in the immediate vicinity of the monitor. Also, patient relocation requires either disconnection of monitoring equipment and a corresponding loss of measurements or an awkward simultaneous movement of patient equipment and cables. Various devices have been proposed or implemented to provide wireless communication links between sensors and monitors, freeing patients from the patient cable tether. These devices, however, are incapable of working with the large installed base of existing monitors and sensors, requiring caregivers and medical institutions to suffer expensive wireless upgrades. It is desirable, therefore, to provide a communications adapter that is plug-compatible both with existing sensors and monitors and that implements a wireless link replacement for the patient cable.

An aspect of a physiological measurement communica-Patient vital sign monitoring may include measurements 40 tions adapter comprises a sensor interface configured to receive a sensor signal. A transmitter modulates a first baseband signal responsive to the sensor signal so as to generate a transmit signal. A receiver demodulates a receive signal corresponding to the transmit signal so as to generate a second baseband signal corresponding to the first baseband signal. Further, a monitor interface is configured to communicate a waveform responsive to the second baseband signal to a sensor port of a monitor. The waveform is adapted to the monitor so that measurements derived by the monitor from the waveform are generally equivalent to measurements derivable from the sensor signal. The communications adapter may further comprise a signal processor having an input in communications with the sensor interface, where the signal processor is operable to derive a parameter responsive to the sensor signal and where the first baseband signal is responsive to the parameter. The parameter may correspond to at least one of a measured oxygen saturation and a pulse rate.

One embodiment may further comprise a waveform generator that synthesizes the waveform from a predetermined shape. The waveform generator synthesizes the waveform at a frequency adjusted to be generally equivalent to the pulse rate. The waveform may have a first amplitude and a second amplitude, and the waveform generator may be configured to adjusted the amplitudes so that measurements derived by the monitor are generally equivalent to a measured oxygen saturation.

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In another embodiment, the sensor interface is operable on the sensor signal to provide a plethysmograph signal output, where the first baseband signal is responsive to the plethysmograph signal. This embodiment may further comprise a waveform modulator that modifies a decoded signal responsive to the second baseband signal to provide the waveform. The waveform modulator may comprise a demodulator that separates a first signal and a second signal from the decoded signal, an amplifier that adjusts amplitudes of the first and second signals to generate a first adjusted signal and a second adjusted signal, and a modulator that combines the first and second adjusted signals into the waveform. The amplitudes of the first and second signals may be responsive to predetermined calibration data for the sensor and the monitor.

An aspect of a physiological measurement communications adapter method comprises the steps of inputting a sensor signal at a patient location, communicating patient data derived from the sensor signal between the patient location and a monitor location, constructing a waveform at the monitor location responsive to the sensor signal, and 20 providing the waveform to a monitor via a sensor port. The waveform is constructed so that the monitor calculates a parameter generally equivalent to a measurement derivable from the sensor signal.

In one embodiment, the communicating step may com- 25 prise the substeps of deriving a conditioned signal from the sensor signal, calculating a parameter signal from the conditioned signal, and transmitting the parameter signal from the patient location to the monitor location. The constructing step may comprise the substep of synthesizing the waveform 30 from the parameter signal. In an alternative embodiment, the communicating step may comprise the substeps of deriving a conditioned signal from said sensor signal and transmitting the conditioned signal from the patient location to the monitor location. The constructing step may comprise the 35 substeps of demodulating the conditioned signal and remodulating the conditioned signal to generate the waveform. The providing step may comprise the substeps of inputting a monitor signal from an LED drive output of the sensor port, modulating the waveform in response to the monitor 40 signal, and outputting the waveform on a detector input of the sensor port.

Another aspect of a physiological measurement communications adapter comprises a sensor interface means for inputting a sensor signal and outputting a conditioned signal, 45 a transmitter means for sending data responsive to the sensor signal, and a receiver means for receiving the data. The communications adapter further comprises a waveform processor means for constructing a waveform from the data so that measurements derived by a monitor from the waveform 50 are generally equivalent to measurements derivable from the sensor signal, and a monitor interface means for communicating the waveform to a sensor port of the monitor. The communications adapter may further comprise a signal processor means for deriving a parameter signal from the 55 conditioned signal, where the data comprises the parameter signal. The waveform processor means may comprise a means for synthesizing the waveform from the parameter signal. The data may comprise the conditioned signal, and the waveform processor means may comprise a means for 60 modulating the conditioned signal in response to the monitor.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is an illustration of a prior art pulse oximetry system:

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FIG. 2 is a functional block diagram of a prior art pulse oximetry system;

FIG. 3 is an illustration of a physiological measurement communications adapter;

FIGS. 4A-B are illustrations of communications adapter sensor modules:

FIGS. **5**A-C are illustrations of communications adapter monitor modules;

FIG. 6 is a functional block diagram of a communications adapter sensor module;

FIG. 7 is a functional block diagram of a communications adapter monitor module;

FIG. 8 is a functional block diagram of a sensor module configured to transmit measured pulse oximeter parameters;

FIG. 9 is a functional block diagram of a monitor module configured to received measured pulse oximeter parameters;

FIG. 10 is a functional block diagram of a sensor module configured to transmit a plethysmograph;

FIG. 11 is a functional block diagram of a monitor module configured to receive a plethysmograph;

FIG. 12 is a functional block diagram of a waveform modulator:

FIG. 13 is a functional block diagram of a sensor module configured for multiple sensors; and

FIG. 14 is a functional block diagram of a monitor module configured for multiple sensors.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Overview

FIG. 3 illustrates one embodiment of a communications adapter. FIGS. 4-5 illustrate physical configurations for a communications adapter. In particular, FIGS. 4A-B illustrate sensor module configurations and FIGS. 5A-C illustrate monitor module configurations. FIGS. 6-14 illustrate communications adapter functions. In particular, FIGS. 6-7 illustrate general functions for a sensor module and a monitor module, respectively. FIGS. 8-9 functionally illustrate a communications adapter where derived pulse oximetry parameters, such as saturation and pulse rate are transmitted between a sensor module and a monitor module. Also, FIGS. 10-12 functionally illustrate a communications adapter where a plethysmograph is transmitted between a sensor module and a monitor module. FIGS. 13-14 functionally illustrate a multiple-parameter communications adapter.

FIG. 3 illustrates a communications adapter 300 having a sensor module 400 and a monitor module 500. The communications adapter 300 communicates patient data derived from a sensor 310 between the sensor module 400, which is located proximate a patient 20 and the monitor module 500, which is located proximate a monitor 360. A wireless link 340 is provided between the sensor module 400 and the monitor module 500, replacing the conventional patient cable, such as a pulse oximetry patient cable 140 (FIG. 1). Advantageously, the sensor module 400 is plug-compatible with a conventional sensor 310. In particular, the sensor connector 318 connects to the sensor module 400 in a similar manner as to a patient cable. Further, the sensor module 400 outputs a drive signal to the sensor 310 and inputs a sensor signal from the sensor 310 in an equivalent manner as a conventional monitor 360. The sensor module 400 may be battery powered or externally powered. External power may be for recharging internal batteries or for powering the sensor module during operation or both.

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As shown in FIG. 3, the monitor module 500 is advantageously plug-compatible with a conventional monitor 360. In particular, the monitor's sensor port 362 connects to the monitor module 500 in a similar manner as to a patient cable, such as a pulse oximetry patient cable 140 (FIG. 1). Further, 5 the monitor module 500 inputs a drive signal from the monitor 360 and outputs a corresponding sensor signal to the monitor 360 in an equivalent manner as a conventional sensor 310. As such, the combination sensor module 400 and monitor module 500 provide a plug-compatible wireless replacement for a patient cable, adapting an existing wired physiological measurement system into a wireless physiological measurement system. The monitor module 500 may be battery powered, powered from the monitor, such as by tapping current from a monitor's LED drive, or externally 15 powered from an independent AC or DC power source.

Although a communications adapter 300 is described herein with respect to a pulse oximetry sensor and monitor, one of ordinary skill in the art will recognize that a communications adapter may provide a plug-compatible wireless replace for a patient cable that connects any physiological sensor and corresponding monitor. For example, a communications adapter 300 may be applied to a biopotential sensor, a non-invasive blood pressure (NIBP) sensor, a respiratory rate sensor, a glucose sensor and the corresponding monitors, to name a few.

Sensor Module Physical Configurations

FIGS. 4A-B illustrate physical embodiments of a sensor module 400. FIG. 4A illustrates a wrist-mounted module 410 having a wrist strap 411, a case 412 and an auxiliary 30 cable 420. The case 412 contains the sensor module electronics, which are functionally described with respect to FIG. 6, below. The case 412 is mounted to the wrist strap 411, which attaches the wrist-mounted module 410 to a patient 20. The auxiliary cable 420 mates to a sensor 35 connector 318 and a module connector 414, providing a wired link between a conventional sensor 310 and the wrist-mounted module 410. Alternatively, the auxiliary cable 420 is directly wired to the sensor module 400. The wrist-mounted module 410 may have a display 415 that 40 shows sensor measurements, module status and other visual indicators, such as monitor status. The wrist-mounted module 410 may also have keys (not shown) or other input mechanisms to control its operational mode and characteristics. In an alternative embodiment, the sensor 310 may 45 have a tail (not shown) that connects directly to the wristmounted module 410, eliminating the auxiliary cable 420.

FIG. 4B illustrates a clip-on module 460 having a clip 461, a case 462 and an auxiliary cable 470. The clip 461 attaches the clip-on module 460 to patient clothing or 50 objects near a patient 20, such as a bed frame. The auxiliary cable 470 mates to the sensor connector 318 and functions as for the auxiliary cable 420 (FIG. 4A) of the wrist-mounted module 410 (FIG. 4A), described above. The clip-on module 460 may have a display 463 and keys 464 as 55 for the wrist-mounted module 410 (FIG. 4A). Either the wrist-mounted module 410 or the clip-on module 460 may have other input or output ports (not shown) that download software, configure the module, or provide a wired connection to other measurement instruments or computing 60 devices, to name a few examples.

Monitor Module Physical Configurations

FIGS. 5A-C illustrate physical embodiments of a monitor module 500. FIG. 5A illustrates a direct-connect module 510 having a case 512 and an integrated monitor connector 514. 65 The case 512 contains the monitor module electronics, which are functionally described with respect to FIG. 7,

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below. The monitor connector **514** mimics that of the monitor end of a patient cable, such as a pulse oximetry patient cable **140** (FIG. 1), and electrically and mechanically connects the monitor module **510** to the monitor **360** via the monitor's sensor port **362**.

FIG. 5B illustrates a cable-connect module 540 having a case 542 and an auxiliary cable 550. The case 542 functions as for the direct-connect module 510 (FIG. 5A), described above. Instead of directly plugging into the monitor 360, the cable-connect module 540 utilizes the auxiliary cable 550, which mimics the monitor end of a patient cable, such as a pulse oximetry patient cable 140 (FIG. 1), and electrically connects the cable-connect module 540 to the monitor sensor port 362.

FIG. 5C illustrates a plug-in module 570 having a plug-in case 572 and an auxiliary cable 580. The plug-in case 572 is mechanically compatible with the plug-in chassis of a multiparameter monitor 370 and may or may not electrically connect to the chassis backplane. The auxiliary cable 580 mimics a patient cable and electrically connects the plug-in module 570 to the sensor port 372 of another plug-in device. A direct-connect module 510 (FIG. 5A) or a cable-connect module 540 (FIG. 5B) may also be used with a multiparameter monitor 370.

In a multiparameter embodiment, such as described with respect to FIGS. 13-14, below, a monitor module 500 may connect to multiple plug-in devices of a multiparameter monitor 370. For example, a cable-connect module 540 (FIG. 5B) may have multiple auxiliary cables 550 (FIG. 5B) that connect to multiple plug-in devices installed within a multiparameter monitor chassis. Similarly, a plug-in module 570 may have one or more auxiliary cables 580 with multiple connectors for attaching to the sensor ports 372 of multiple plug-in devices.

Communications Adapter Functions

FIGS. 6-7 illustrate functional embodiments of a communications adapter. FIG. 6 illustrates a sensor module 400 having a sensor interface 610, a signal processor 630, an encoder 640, a transmitter 650 and a transmitting antenna 670. A physiological sensor 310 provides an input sensor signal 612 at the sensor connector 318. Depending on the sensor 310, the sensor module 400 may provide one or more drive signals 618 to the sensor 310. The sensor interface 610 inputs the sensor signal 612 and outputs a conditioned signal 614. The conditioned signal 614 may be coupled to the transmitter 650 or further processed by a signal processor 630. If the sensor module configuration utilizes a signal processor 630, it derives a parameter signal 632 responsive to the sensor signal 612, which is then coupled to the transmitter 650. Regardless, the transmitter 650 inputs a baseband signal 642 that is responsive to the sensor signal **612**. The transmitter **650** modulates the baseband signal **642** with a carrier to generate a transmit signal 654. The transmit signal 654 may be derived by various amplitude, frequency or phase modulation schemes, as is well known in the art. The transmit signal 654 is coupled to the transmit antenna 670, which provides wireless communications to a corresponding receive antenna 770 (FIG. 7), as described below.

As shown in FIG. 6, the sensor interface 610 conditions and digitizes the sensor signal 612 to generate the conditioned signal 614. Sensor signal conditioning may be performed in the analog domain or digital domain or both and may include amplification and filtering in the analog domain and filtering, buffering and data rate modification in the digital domain, to name a few. The resulting conditioned signal 614 is responsive to the sensor signal 612 and may be used to calculate or derive a parameter signal 632.

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Further shown in FIG. 6, the signal processor 630 performs signal processing on the conditioned signal 614 to generate the parameter signal 632. The signal processing may include buffering, digital filtering, smoothing, averaging, adaptive filtering and frequency transforms to name a 5 few. The resulting parameter signal 632 may be a measurement calculated or derived from the conditioned signal, such as oxygen saturation, pulse rate, blood glucose, blood pressure and EKG to name a few. Also, the parameter signal 632 may be an intermediate result from which the above-stated 10 measurements may be calculated or derived.

As described above, the sensor interface 610 performs mixed analog and digital pre-processing of an analog sensor signal and provides a digital output signal to the signal processor 630. The signal processor 630 then performs 15 digital post-processing of the front-end processor output. In alternative embodiments, the input sensor signal 612 and the output conditioned signal 614 may be either analog or digital, the front-end processing may be purely analog or purely digital, and the back-end processing may be purely 20 analog or mixed analog or digital.

In addition, FIG. 6 shows an encoder 640, which translates a digital word or serial bit stream, for example, into the baseband signal 642, as is well-known in the art. The baseband signal 642 comprises the symbol stream that 25 drives the transmit signal 654 modulation, and may be a single signal or multiple related signal components, such as in-phase and quadrature signals. The encoder 640 may include data compression and redundancy, also well-known in the art.

FIG. 7 illustrates a monitor module 500 having a receive antenna 770, a receiver 710, a decoder 720, a waveform processor 730 and a monitor interface 750. A receive signal 712 is coupled from the receive antenna 770, which provides wireless communications to a corresponding transmit 35 antenna 670 (FIG. 6), as described above. The receiver 710 inputs the receive signal 712, which corresponds to the transmit signal 654 (FIG. 6). The receiver 710 demodulates the receive signal to generate a baseband signal 714. The decoder 720 translates the symbols of the demodulated 40 baseband signal 714 into a decoded signal 724, such as a digital word stream or bit stream. The waveform processor 730 inputs the decoded signal 724 and generates a constructed signal 732. The monitor interface 750 is configured to communicate the constructed signal 732 to a sensor port 45 362 of a monitor 360. The monitor 360 may output a sensor drive signal 754, which the monitor interface 750 inputs to the waveform processor 730 as a monitor drive signal 734. The waveform processor 730 may utilize the monitor drive signal 734 to generate the constructed signal 732. The 50 monitor interface 750 may also provide characterization information 758 to the waveform processor 730, relating to the monitor 360, the sensor 310 or both, that the waveform processor 730 utilizes to generate the constructed signal 732.

The constructed signal **732** is adapted to the monitor **360** 55 so that measurements derived by the monitor **360** from the constructed signal **732** are generally equivalent to measurements derivable from the sensor signal **612** (FIG. **6**). Note that the sensor **310** (FIG. **6**) may or may not be directly compatible with the monitor **360**. If the sensor **310** (FIG. **6**) 60 is compatible with the monitor **360**, the constructed signal **732** is generated so that measurements derived by the monitor **360** from the constructed signal **732** are generally equivalent (within clinical significance) with those derivable directly from the sensor signal **612** (FIG. **6**). If the sensor 65 **310** (FIG. **6**) is not compatible with the monitor **360**, the constructed signal **732** is generated so that measurements

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derived by the monitor 360 from the constructed signal 732 are generally equivalent to those derivable directly from the sensor signal 612 (FIG. 6) using a compatible monitor. Wireless Pulse Oximetry

FIGS. **8-11** illustrate pulse oximeter embodiments of a communications adapter. FIGS. **8-9** illustrate a sensor module and a monitor module, respectively, configured to communicate measured pulse oximeter parameters. FIG. **10-11** illustrate a sensor module and a monitor module, respectively, configured to communicate a plethysmograph signal. Parameter Transmission

FIG. 8 illustrates a pulse oximetry sensor module 800 having a sensor interface 810, signal processor 830, encoder 840, transmitter 850, transmitting antenna 870 and controller 890. The sensor interface 810, signal processor 830 and controller 890 function as described with respect to FIG. 2, above. The sensor interface 810 communicates with a standard pulse oximetry sensor 310, providing an LED drive signal 818 to the LED emitters 312 and receiving a sensor signal 812 from the detector 314 in response. The sensor interface 810 provides front-end processing of the sensor signal 812, also described above, providing a plethysmograph signal 814 to the signal processor 830. The signal processor 830 then derives a parameter signal 832 that comprises a real time measurement of oxygen saturation and pulse rate. The parameter signal 832 may include other parameters, such as measurements of perfusion index and signal quality. In one embodiment, the signal processor is an MS-5 or MS-7 board available from Masimo Corporation, Irvine. Calif.

As shown in FIG. 8, the encoder 840, the transmitter 850 and the transmitting antenna 870 function as described with respect to FIG. 6, above. For example, the parameter signal 832 may be a digital word stream that is serialized into a bit stream and encoded into a baseband signal 842. The baseband signal 842 may be, for example, two bit symbols that drive a quadrature phase shift keyed (QPSK) modulator in the transmitter 850. Other encodings and modulations are also applicable, as described above. The transmitter 850 inputs the baseband signal 842 and generates a transmit signal 854 that is a modulated carrier having a frequency suitable for short-range transmission, such as within a hospital room, doctor's office, emergency vehicle or critical care ward, to name a few. The transmit signal 854 is coupled to the transmit antenna 870, which provides wireless communications to a corresponding receive antenna 970 (FIG. 9), as described below.

FIG. 9 illustrates a monitor module 900 having a receive antenna 970, a receiver 910, a decoder 920, a waveform generator 930 and an interface cable 950. The receive antenna 970, receiver 910 and decoder 920 function as described with respect to FIG. 7, above. In particular, the receive signal 912 is coupled from the receive antenna 970, which provides wireless communications to a corresponding transmit antenna 870 (FIG. 8). The receiver 910 inputs the receive signal 912, which corresponds to the transmit signal 854 (FIG. 8). The receiver 810 demodulates the receive signal 912 to generate a baseband signal 914. Not accounting for transmission errors, the baseband signal 914 corresponds to the sensor module baseband signal 842 (FIG. 8), for example a symbol stream of two bits each. The decoder 920 assembles the baseband signal 914 into a parameter signal 924, which, for example, may be a sequence of digital words corresponding to oxygen saturation and pulse rate. Again, not accounting for transmission errors, the monitor

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module parameter signal 924 corresponds to the sensor module parameter signal 832 (FIG. 8), derived by the signal processor 830 (FIG. 8).

Also shown in FIG. 9, the waveform generator 930 is a particular embodiment of the waveform processor 730 (FIG. 5 7) described above. The waveform generator 930 generates a synthesized waveform 932 that the pulse oximeter monitor 360 can process to calculate SpO2 and pulse rate values or exception messages. In the present embodiment, the waveform generator output does not reflect a physiological waveform. In particular, the synthesized waveform is not physiological data from the sensor module 800, but is a waveform synthesized from predetermined stored waveform data to cause the monitor 360 to calculate oxygen saturation and pulse rate equivalent to or generally equivalent (within 15 clinical significance) to that calculated by the signal processor 830 (FIG. 8). The actual intensity signal from the patient received by the detector 314 (FIG. 8) is not provided to the monitor 360 in the present embodiment. Indeed, the waveform provided to the monitor 360 will usually not resemble 20 a plethysmographic waveform or other physiological data from the patient to whom the sensor module 800 (FIG. 8) is

The synthesized waveform 932 is modulated according to the drive signal input 934. That is, the pulse oximeter 25 monitor 360 expects to receive a red and IR modulated intensity signal originating from a detector, as described with respect to FIGS. 1-2, above. The waveform generator 930 generates the synthesized waveform 932 with a predetermined shape, such as a triangular or sawtooth waveform 30 stored in waveform generator memory or derived by a waveform generator algorithm. The waveform is modulated synchronously with the drive input 934 with first and second amplitudes that are processed in the monitor 360 as red and IR portions of a sensor signal. The frequency and the first 35 and second amplitudes are adjusted so that pulse rate and oxygen saturation measurements derived by the pulse oximeter monitor 360 are generally equivalent to the parameter measurements derived by the signal processor 830 (FIG. 8), as described above. One embodiment of a waveform gen- 40 erator 930 is described in U.S. Patent Application No. 60/117,097 entitled "Universal/Upgrading Pulse Oximeter," assigned to Masimo Corporation, Irvine, Calif. and incorporated by reference herein. Although the waveform generator 930 is described above as synthesizing a waveform 45 that does not resemble a physiological signal, one of ordinary skill will recognize that another embodiment of the waveform generator 930 could incorporate, for example, a plethysmograph simulator or other physiological signal simulator.

Further shown in FIG. 9, the interface cable 950 functions in a manner similar to the monitor interface 750 (FIG. 7) described above. The interface cable 950 is configured to communicate the synthesized waveform 932 to the monitor **360** sensor port and to communicate the sensor drive signal 55 934 to the waveform generator 930. The interface cable 950 may include a ROM 960 that contains monitor and sensor characterization data. The ROM 960 is read by the waveform generator 930 so that the synthesized waveform 932 is adapted to a particular monitor 360. For example, the ROM 60 960 may contain calibration data of red/IR versus oxygen saturation, waveform amplitude and waveform shape information. An interface cable is described in U.S. Patent Application No. 60/117,092, referenced above. Monitorspecific SatShare™ brand interface cables are available 65 from Masimo Corporation, Irvine, Calif. In an alternative embodiment, such as a direct connect monitor module as

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illustrated in FIG. 5A, an interface cable 950 is not used and the ROM 960 may be incorporated within the monitor module 900 itself.

Plethysmograph Transmission

FIG. 10 illustrates another pulse oximetry sensor module 1000 having a sensor interface 1010, encoder 1040, transmitter 1050, transmitting antenna 1070 and controller 1090, which have the corresponding functions as those described with respect to FIG. 8, above. The encoder 1040, however, inputs a plethysmograph signal 1014 rather than oxygen saturation and pulse rate measurements 832 (FIG. 8). Thus, the sensor module 1000 according to this embodiment encodes and transmits a plethysmograph signal 1014 to a corresponding monitor module 1100 (FIG. 11) in contrast to derived physiological parameters, such as oxygen saturation and pulse rate. The plethysmograph signal 1014 is illustrated in FIG. 10 as being a direct output from the sensor interface 1010. In another embodiment, the sensor module 1000 incorporates a decimation processor, not shown, after the sensor interface 1010 so as to provide a plethysmograph signal 1014 having a reduced sample rate.

FIG. 11 illustrates another pulse oximetry monitor module 1100 having a receive antenna 1170, a receiver 1110, a decoder 1120 and an interface cable 1150, which have the corresponding functions as those described with respect to FIG. 9, above. This monitor module embodiment 1100, however, has a waveform modulator 1200 rather than a waveform generator 930 (FIG. 9), as described above. The waveform modulator 1200 inputs a plethysmograph signal from the decoder 1120 rather than oxygen saturation and pulse rate measurements, as described with respect to FIG. 9, above. Further, the waveform modulator 1200 provides an modulated waveform 1132 to the pulse oximeter monitor 360 rather than a synthesized waveform, as described with respect to FIG. 9. The modulated waveform 1132 is a plethysmographic waveform modulated according to the monitor drive signal input 1134. That is, the waveform modulator 1200 does not synthesize a waveform, but rather modifies the received plethysmograph signal 1124 to cause the monitor 360 to calculate oxygen saturation and pulse rate generally equivalent (within clinical significance) to that derivable by a compatible, calibrated pulse oximeter directly from the sensor signal 1012 (FIG. 10). The waveform modulator 1200 is described in further detail with respect to FIG. 12, below.

FIG. 12 shows a waveform modulator 1200 having a demodulator 1210, a red digital-to-analog converter (DAC) 1220, an IR DAC 1230, a red amplifier 1240, an IR amplifier 1250, a modulator 1260, a modulator control 1270, a look-up table (LUT) 1280 and a ratio calculator 1290. The waveform modulator 1200 demodulates red and IR plethysmographs ("pleths") from the decoder output 1124 into a separate red pleth 1222 and IR pleth 1232. The waveform modulator 1200 also adjusts the amplitudes of the pleths 1222, 1232 according to stored calibration curves for the sensor 310 (FIG. 10) and the monitor 360 (FIG. 11). Further, the waveform modulator 1200 re-modulates the adjusted red pleth 1242 and adjusted IR pleth 1252, generating a modulated waveform 1132 to the monitor 360 (FIG. 11).

As shown in FIG. 12, the demodulator 1210 performs the demodulation function described above, generating digital red and IR pleth signals 1212, 1214. The DACs 1220, 1230 convert the digital pleth signals 1212, 1214 to corresponding analog pleth signals 1222, 1232. The amplifiers 1240, 1250 have variable gain control inputs 1262, 1264 and perform the amplitude adjustment function described above, generating adjusted red and IR pleth signals 1242, 1252. The

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modulator 1260 performs the re-modulation function described above, combining the adjusted red and IR pleth signals 1242, 1252 according to a control signal 1272. The modulator control 1270 generates the control signal 1272 synchronously with the LED drive signal(s) 1134 from the 5 monitor 360.

Also shown in FIG. 12, the ratio calculator 1290 derives a red/IR ratio from the demodulator outputs 1212, 1214. The LUT 1280 stores empirical calibration data for the sensor 310 (FIG. 10). The LUT 1280 also downloads monitorspecific calibration data from the ROM 1160 (FIG. 11) via the ROM output 1158. From this calibration data, the LUT 1280 determines a desired red/IR ratio for the modulated waveform 1132 and generates red and IR gain outputs 1262, 1264 to the corresponding amplifiers 1240, 1250, accordingly. A desired red/IR ratio is one that allows the monitor 360 (FIG. 11) to derive oxygen saturation measurements from the modulated waveform 1132 that are generally equivalent to that derivable directly from the sensor signal 1012 (FIG. 10).

One of ordinary skill in the art will recognize that some of the signal processing functions described with respect to FIGS. **8-11** may be performed either within a sensor module or within a monitor module. Signal processing functions performed within a sensor module may advantageously 25 reduce the transmission bandwidth to a monitor module at a cost of increased sensor module size and power consumption. Likewise, signal processing functions performed within a monitor module may reduce sensor module size and power consumption at a cost of increase transmission bandwidth.

For example, a monitor module embodiment 900 (FIG. 9) described above receives measured pulse oximeter parameters, such as oxygen saturation and pulse rate, and generates a corresponding synthesized waveform. In that embodi- 35 ment, the oxygen saturation and pulse rate computations are performed within a sensor module 800 (FIG. 8). Another monitor module embodiment 1100 (FIG. 11), also described above, receives a plethysmograph waveform and generates a remodulated waveform. In that embodiment, minimal 40 signal processing is performed within a sensor module 1000 (FIG. 10). In yet another embodiment, not shown, a sensor module transmits a plethysmograph waveform or a decimated plethysmograph waveform having a reduced sample rate. A corresponding monitor module has a signal proces- 45 sor, such as described with respect to FIG. 8, in addition to a waveform generator, as described with respect to FIG. 9. The signal processor computes pulse oximeter parameters and the waveform generator generates a corresponding synthesized waveform, as described above. In this embodi- 50 ment, minimal signal processing is performed within the sensor module, and the monitor module functions are performed on the pulse oximeter parameters computed within the monitor module.

Wireless Multiple Parameter Measurements

FIGS. 13-14 illustrate a multiple parameter communications adapter. FIG. 13 illustrates a multiple parameter sensor module 1300 having sensor interfaces 1310, one or more signal processors 1330, a multiplexer and encoder 1340, a transmitter 1350, a transmitting antenna 1370 and a controller 1390. One or more physiological sensors 1301 provide input sensor signals 1312 to the sensor module 1300. Depending on the particular sensors 1301, the sensor module 1300 may provide one or more drive signals 1312 to the sensors 1301 as determined by the controller 1390. The 65 sensor interfaces 1310 input the sensor signals 1312 and output one or more conditioned signals 1314. The condi-

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tioned signals 1314 may be coupled to the transmitter 1350 or further processed by the signal processors 1330. If the sensor module configuration utilizes signal processors 1330, it derives multiple parameter signals 1332 responsive to the sensor signals 1312, which are then coupled to the transmitter 1350. Regardless, the transmitter 1350 inputs a baseband signal 1342 that is responsive to the sensor signals 1312. The transmitter 1350 modulates the baseband signal 1342 with a carrier to generate a transmit signal 1354, which is coupled to the transmit antenna 1370 and communicated to a corresponding receive antenna 1470 (FIG. 14), as described with respect to FIG. 6, above. Alternatively, there may be multiple baseband signals 1342, and the transmitter 1350 may transmit on multiple frequency channels, where each channel coveys data responsive to one or more of the sensor signals 1314.

As shown in FIG. 13, the sensor interface 1310 conditions and digitizes the sensor signals 1312 as described for a single sensor with respect to FIG. 6, above. The resulting 20 conditioned signals **1314** are responsive to the sensor signals 1312. The signal processors 1330 perform signal processing on the conditioned signals 1314 to derive parameter signals 1332, as described for a single conditioned signal with respect to FIG. 6, above. The parameter signals 1332 may be physiological measurements such as oxygen saturation, pulse rate, blood glucose, blood pressure, EKG, respiration rate and body temperature to name a few, or may be intermediate results from which the above-stated measurements may be calculated or derived. The multiplexer and encoder 1340 combines multiple digital word or serial bit streams into a single digital word or bit stream. The multiplexer and encoder also encodes the digital word or bit stream to generate the baseband signal 1342, as described with respect to FIG. 6, above.

FIG. 14 illustrates a multiple parameter monitor module 1400 having a receive antenna 1470, a receiver 1410, a demultiplexer and decoder 1420, one or more waveform processors 1430 and a monitor interface 1450. The receiver 1410 inputs and demodulates the receive signal 1412 corresponding to the transmit signal 1354 (FIG. 13) to generate a baseband signal **1414** as described with respect to FIG. **7**, above. The demultiplexer and decoder 1420 separates the symbol streams corresponding to the multiple conditioned signals 1314 (FIG. 13) and/or parameter signals 1332 (FIG. 13) and translates these symbol streams into multiple decoded signals 1422, as described for a single symbol stream with respect to FIG. 7, above. Alternatively, multiple frequency channels are received to generate multiple baseband signals, each of which are decoded to yield multiple decoded signals 1422. The waveform processors 1430 input the decoded signals 1422 and generate multiple constructed signals 1432, as described for a single decoded signal with respect to FIGS. 7-12, above. The monitor interface 1450 is configured to communicate the constructed signals 1432 to the sensor ports of a multiple parameter monitor 1401 or multiple single parameter monitors, in a manner similar to that for a single constructed signal, as described with respect to FIGS. 7-12, above. In particular, the constructed signals **1432** are adapted to the monitor **1401** so that measurements derived by the monitor 1401 from the constructed signals 1432 are generally equivalent to measurements derivable directly from the sensor signals 1312 (FIG. 13).

A physiological measurement communications adapter is described above with respect to wireless communications and, in particular, radio frequency communications. A sensor module and monitor module, however, may also communicate via wired communications, such as telephone, Internet

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or fiberoptic cable to name a few. Further, wireless communications can also utilize light frequencies, such as IR or laser to name a few.

A physiological measurement communications adapter has been disclosed in detail in connection with various 5 embodiments. These embodiments are disclosed by way of examples only. One of ordinary skill in the art will appreciate many variations and modifications of a physiological measurement communications adapter within the scope of the claims that follow.

What is claimed is:

- 1. A wearable, portable physiological monitor configured to wirelessly transmit real time information regarding a plurality physiological parameters, the portable monitor comprising:
 - a plurality of sensor ports positioned on a housing of the portable monitor and configured to provide respective wired interfaces with different respective physiological sensors of a plurality of physiological sensors, wherein: at least a first sensor port of the plurality of sensor ports 20 is positioned on a side of the housing of the portable monitor such that, when the portable monitor is attached to an arm of a patient, a wired connection extending from the first sensor port to a first physiological sensor positioned on a digit of the patient 25 follows a path to the digit of the patient that is substantially perpendicular to the side of the housing and avoids tangling of the wired connection;

one or more processing devices configured to:

- receive, via the plurality of sensor ports, a plurality of 30 signals from the plurality of physiological sensors, at least some of the plurality of signals including digital information, and at least some of the plurality of signals including analog information;
- cause to be displayed, on a display of the portable 35 attached to the arm of the patient. monitor, a plurality of physiological parameters values responsive to the plurality of signals;
- combine information indicative of the plurality of signals into a single digital word or bit stream; and encode the single digital word or bit stream to generate 40 a baseband signal; and
- a transmitter configured to:
 - modulate the baseband signal with a carrier to generate a transmit signal; and
 - wirelessly transmit the transmit signal to a remote 45 patient monitoring device configured to decode the signal and display, on a remote display, the plurality of physiological parameters values responsive to the plurality of signals.
- 2. The portable monitor of claim 1, wherein the one or 50 more processing devices are further configured to:
 - process, at least in part in the analog domain, at least a first signal of the plurality of signals to determine at least a first one or more of the plurality of physiological parameters values; and
 - process, at least in part in the digital domain, at least a second signal of the plurality of signals to determine at least a second one or more of the plurality of physiological parameters values.
- 3. The portable monitor of claim 2, wherein the first signal 60 is received via the first sensor port from the first physiological sensor.
- 4. The portable monitor of claim 3, wherein the first physiological sensor comprises a pulse oximetry sensor.
- 5. The portable monitor of claim 4, wherein the first one 65 or more of the plurality of physiological parameters values comprises at least oxygen saturation and pulse rate.

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- 6. The portable monitor of claim 2, wherein the one or more processing devices comprise:
 - a multiplexer configured to combine the information indicative of the plurality of signals into the single digital word or bit stream; and
 - an encoder configured to encode the single digital word or bit stream to generate the baseband signal.
- 7. The portable monitor of claim 6, wherein the baseband signal comprises a single signal.
- 8. The portable monitor of claim 6, wherein the baseband signal comprises multiple related signal components including at least one of: in-phase signals or quadrature signals.
- 9. The portable monitor of claim 6, wherein the transmitter is further configured to transmit on multiple frequency 15 channels.
 - 10. The portable monitor of claim 1, wherein the plurality of sensor ports comprise at least:
 - a second sensor port configured to receive a signal from an EKG sensor arrangement; and
 - a third sensor port configured to receive a signal from a blood pressure sensor arrangement.
 - 11. The portable monitor of claim 10 further comprising: a plurality of sensor interfaces configured to receive the plurality of signals and initially process the plurality of signals, wherein:
 - each of the plurality of sensor interfaces is associated with a respective sensor port of the plurality of sensor ports, and
 - each of the plurality of sensor interfaces is configured to receive a signal from a respective physiological sensor of the plurality of physiological sensors.
 - 12. The portable monitor of claim 1, wherein a face of the housing comprises a single user interface, and the face of the housing is viewable by a user when the portable monitor is
 - 13. The portable monitor of claim 12, wherein the single user interface comprises the display.
 - 14. The portable monitor of claim 13, wherein the display is positioned centrally on the face of the housing.
 - 15. The portable monitor of claim 14, wherein the display positioned on the face of the housing is sized such that the display covers more than half of a length of a shortest dimension of the face of the housing.
 - 16. A battery-powered wearable physiological monitoring device configured to communicate with multiple types of sensor arrangements via a plurality of sensor interfaces, the wearable physiological monitoring device comprising:
 - a plurality of sensor communication ports including:
 - a first sensor communication port configured to provide wired communication with a first type of physiological sensor arrangement, wherein the first sensor port is positioned on the device such that a wire extending from the first sensor communication port to the first type of physiological sensor arrangement extends from the device along an axis perpendicular to a face of the device upon which the first sensor port is
 - a second sensor communication port configured to provide wired communication with a second type of physiological sensor arrangement different from the first type of physiological sensor arrangement; and
 - a third sensor communication port configured to provide wired communication with a third type of physiological sensor arrangement different from both the first and second types of physiological sensor arrangements;
 - a plurality of sensor interfaces including:

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- a first sensor interface configured to receive a first signal from a first sensor arrangement of the first type, the first signal including analog information;
- a second sensor interface configured to receive a second signal from a second sensor arrangement of the second type the second signal including digital information; and
- a third sensor interface configured to receive a third signal from a third sensor arrangement of the third type;
- wherein the plurality of sensor interfaces are configured to output one or more signals indicative of physiological parameters sensed by the first, second, and third sensor arrangements;
- a display positioned on a face of the wearable physiological monitoring device configured to display information while the wearable physiological monitoring device is being worn by a patient;
- a processor configured to:
 - responsive to the one or more signals indicative of the physiological parameters, cause to be displayed, on the display, physiological parameter measurements; combine information indicative of the one or more signals into a single digital word or bit stream; and 25 encode the single digital word or bit stream to generate
- a baseband signal; a transmitter configured to:
 - modulate the baseband signal with a carrier to generate a transmit signal; and

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- wirelessly transmit the transmit signal to a receiving patient monitoring device that is not wired to the wearable physiological monitoring device; and
- a battery configured to provide power to at least the processor, the display, the transmitter, and the first sensor arrangement via the first sensor communication port such that the wearable physiological monitoring device is portable and wearable by a patient.
- 17. The wearable physiological monitoring device of claim 16, wherein:
 - at least one of the first, second, or third sensor interfaces is configured to process signals at least in part in the analog domain; and
 - at least at different one of the first, second, or third sensor interfaces is configured to process signals at least in part in the digital domain.
- 18. The wearable physiological monitoring device of claim 17, wherein the first sensor arrangement comprises a pulse oximetry sensor configured to be attached to a digit of a patient.
- 19. The wearable physiological monitoring device of claim 18, wherein the first sensor port is positioned on a side of the wearable physiological monitoring device that faces a hand of a patient when the wearable physiological monitoring device is attached to an arm of the hand of the patient.
- 20. The wearable physiological monitoring device of claim 19, wherein the face of the wearable physiological monitoring device comprises a single user interface, and the single user interface comprises the display.

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(54) ARM MOUNTABLE PORTABLE PATIENT MONITOR

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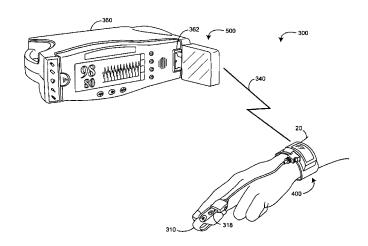
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(57) ABSTRACT

An arm mountable portable patient monitoring device configured for both on patient monitoring of parameter measurements using one or more sensors operatively connected to the portable patient monitoring device and wireless transmission of parameter measurements. The arm mountable portable patient monitoring device includes a pulse oximetry sensor configured to be wrapped around a digit of a patient, a housing having a size and shape configured for mounting to a lower arm of the patient, and a strap mountable to the back side of the housing and configured to secure the housing to the lower arm of the patient. The housing includes a display, a first sensor port positioned on the housing to face toward a hand of the patient, second and third sensor ports, a battery, signal processing arrangements to cause display of parameter measurements, and a transmitter to transmit information indicative of the measurements.

20 Claims, 17 Drawing Sheets



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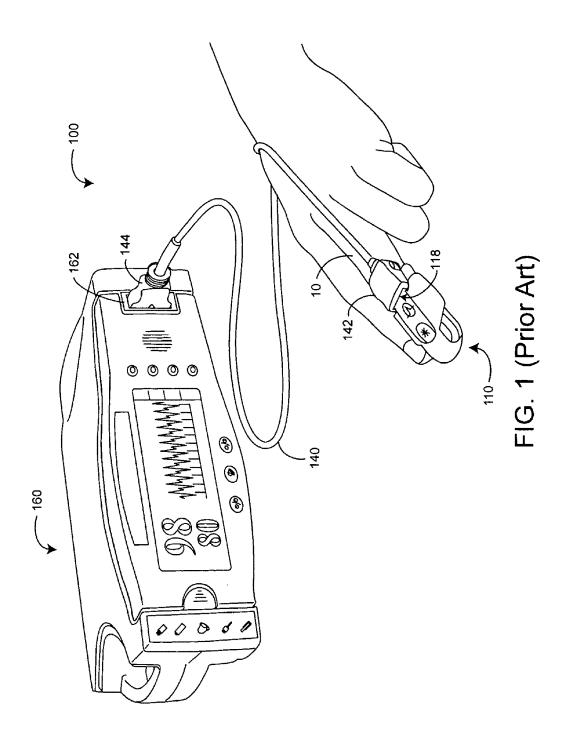
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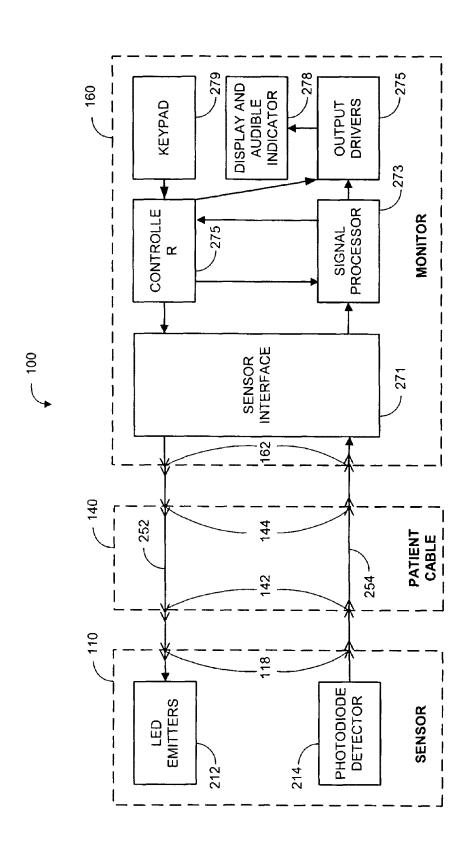
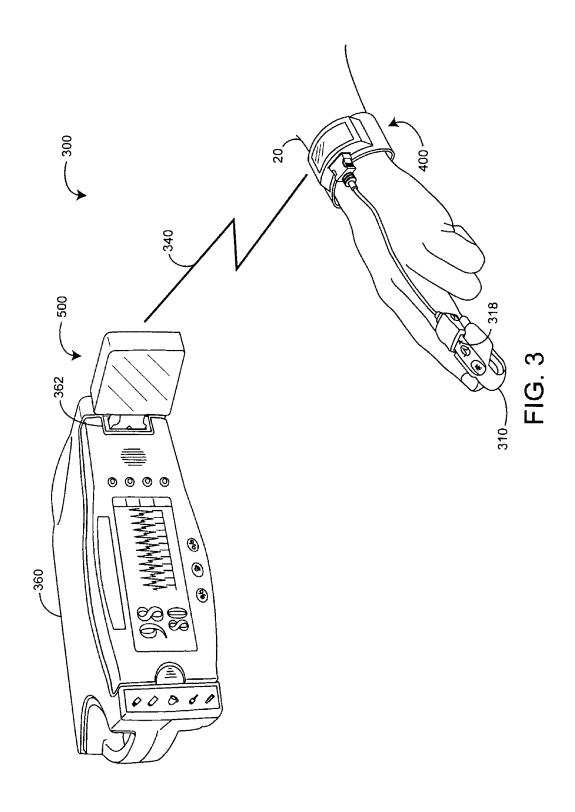


FIG. 2 (Prior Art)

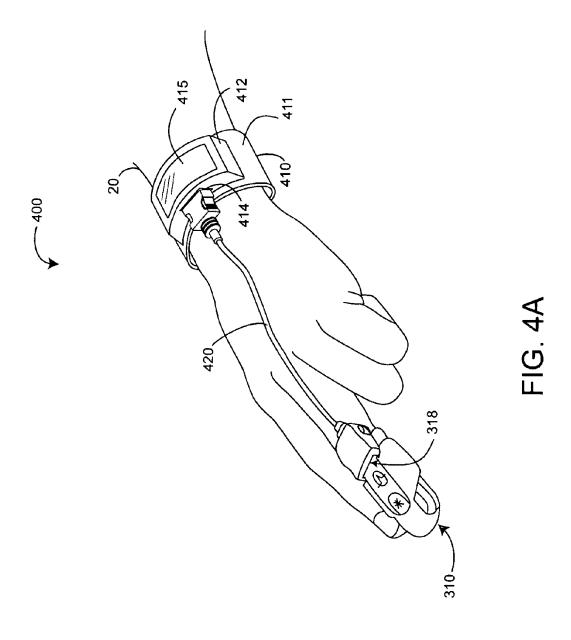
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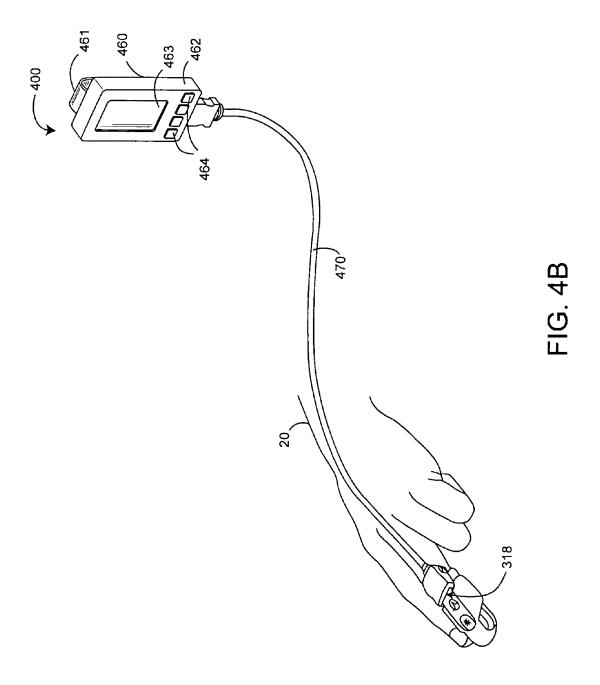
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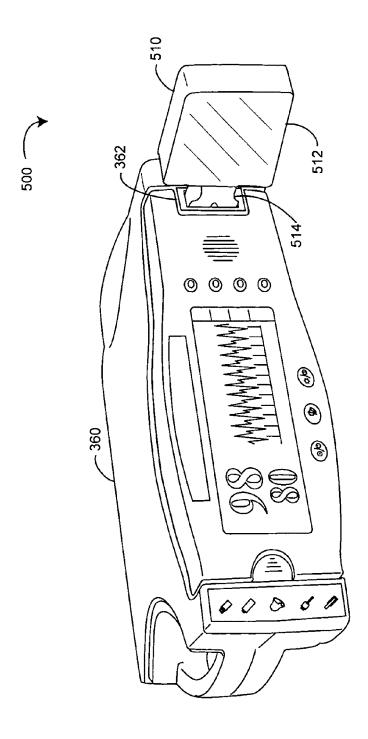


FIG. 5A

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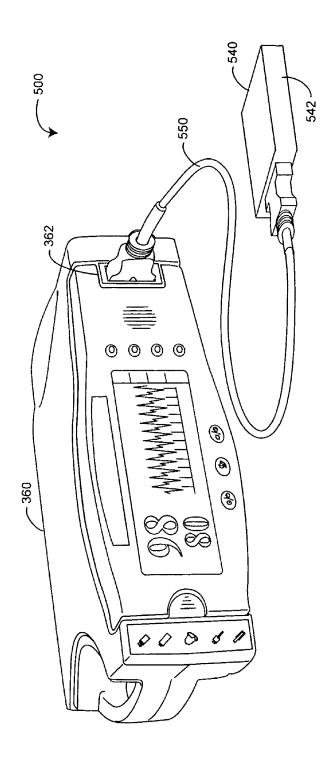
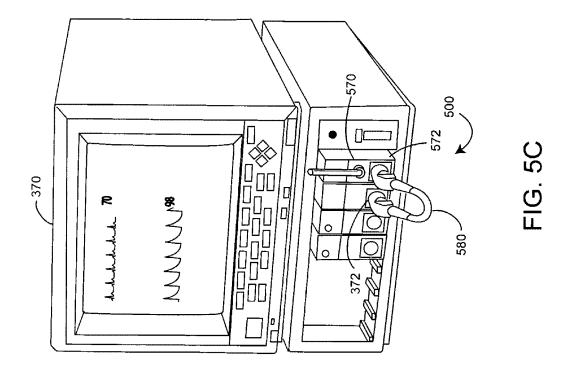


FIG. 5B

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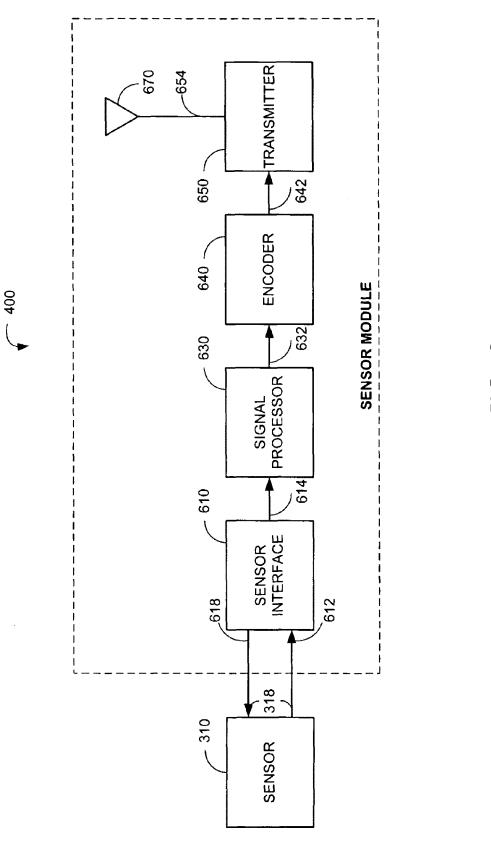


FIG. 6

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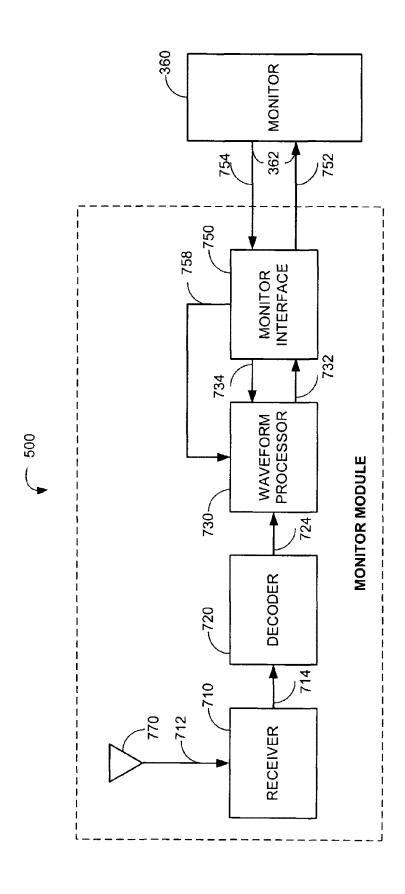


FIG. 7

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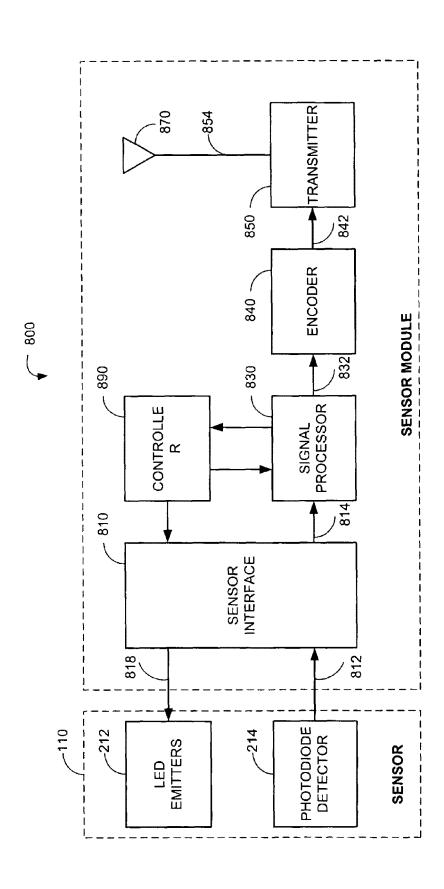


FIG. 8

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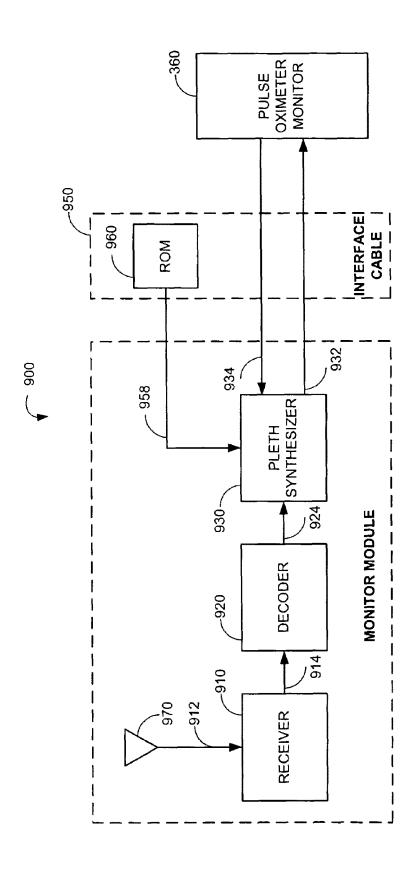


FIG. 9

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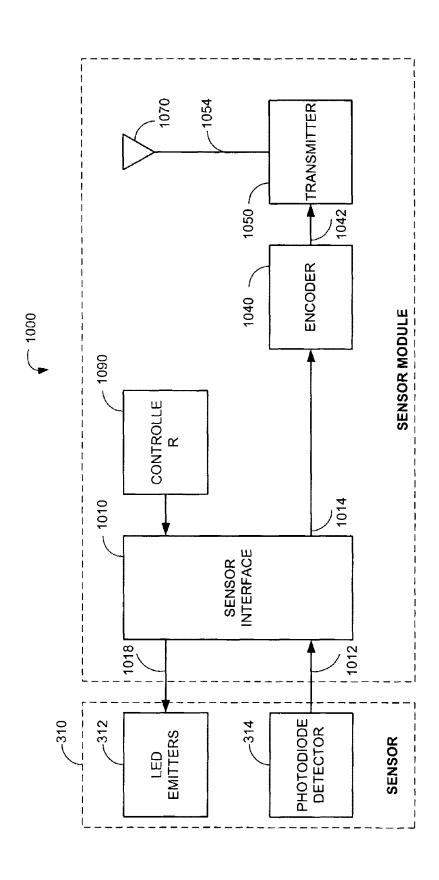


FIG. 10

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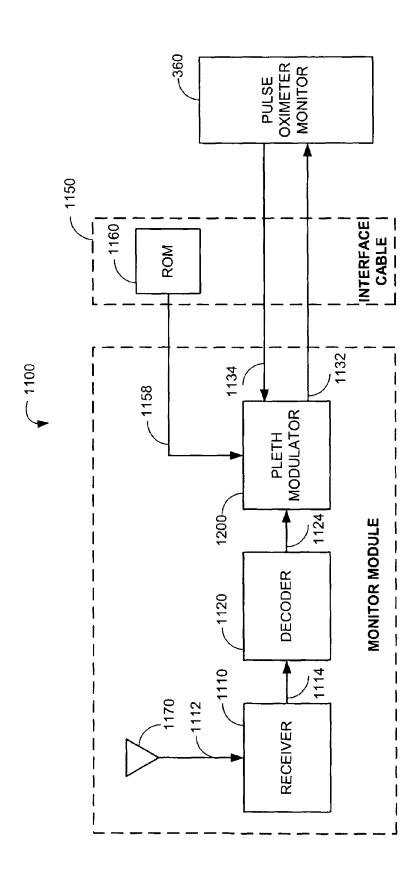
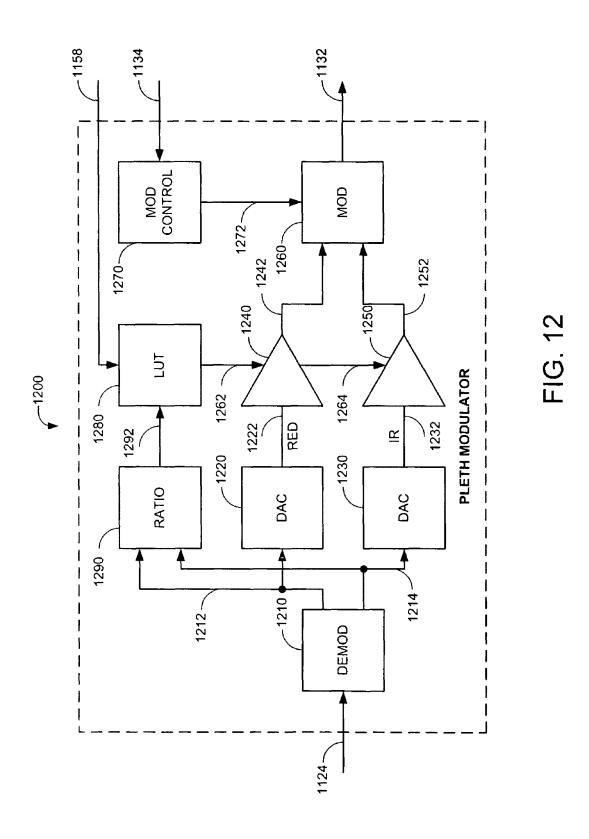


FIG. 11

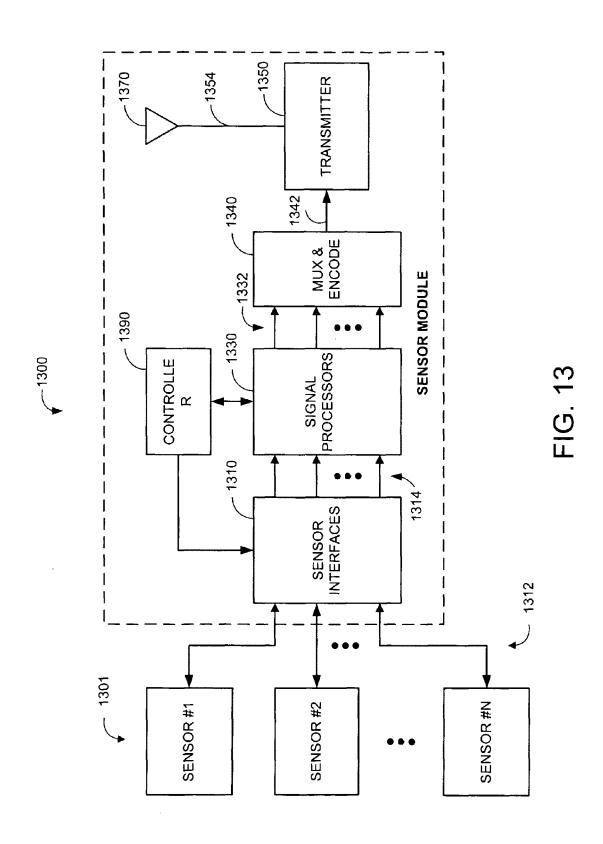
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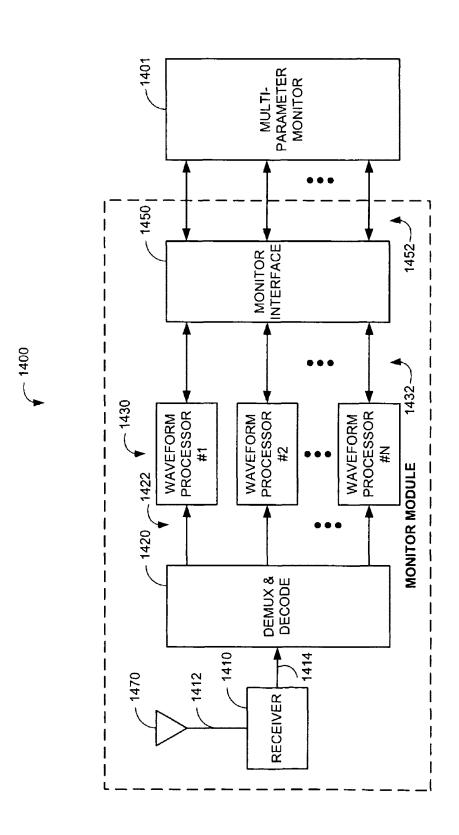


FIG. 14

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ARM MOUNTABLE PORTABLE PATIENT **MONITOR**

REFERENCE TO RELATED APPLICATION

The present application is a continuation of U.S. patent application Ser. No. 15/448,989, filed on Mar. 3, 2017, entitled "Physiological Measurement Communications Adapter," which is a continuation of U.S. patent application Ser. No. 14/815,232, filed on Jul. 31, 2015, entitled "Physi-10" ological Measurement Communications Adapter," which is a continuation of U.S. patent application Ser. No. 14/217, 788, filed on Mar. 18, 2014, entitled "Wrist-Mounted Physiological Measurement Device," now U.S. Pat. No. 9,113, 832, which is a continuation of U.S. patent application Ser. 15 No. 14/037,137, filed on Sep. 25, 2013, entitled "Physiological Measurement Communications Adapter," now U.S. Pat. No. 9,113,831, which is a continuation of U.S. patent application Ser. No. 12/955,826, filed on Nov. 29, 2010, entitled "Physiological Measurement Communications 20 Adapter," now U.S. Pat. No. 8,548,548, which is a continuation of U.S. patent application Ser. No. 11/417,006, filed on May 3, 2006, entitled "Physiological Measurement Communications Adapter," now U.S. Pat. No. 7,844,315, which claims priority benefit under 35 U.S.C. §120 to, and is a 25 continuation of, U.S. patent application Ser. No. 11/048,330, filed Feb. 1, 2005, entitled "Physiological Measurement Communications Adapter," now U.S. Pat. No. 7,844,314, which is a continuation of U.S. patent application Ser. No. 10/377,933, entitled "Physiological Measurement Commu-30 nications Adapter," now U.S. Pat. No. 6,850,788, which claims priority benefit under 35 U.S.C. §119(e) from U.S. Provisional Application No. 60/367,428, filed Mar. 25, 2002, entitled "Physiological Measurement Communications Adapter." The present application also incorporates the 35 foregoing utility disclosures herein by reference.

BACKGROUND OF THE INVENTION

of blood oxygen, blood pressure, respiratory gas, and EKG among other parameters. Each of these physiological parameters typically requires a sensor in contact with a patient and a cable connecting the sensor to a monitoring device. For example, FIGS. 1-2 illustrate a conventional pulse oximetry 45 system 100 used for the measurement of blood oxygen. As shown in FIG. 1, a pulse oximetry system has a sensor 110. a patient cable 140 and a monitor 160. The sensor 110 is typically attached to a finger 10 as shown. The sensor 110 has a plug 118 that inserts into a patient cable socket 142. 50 The monitor 160 has a socket 162 that accepts a patient cable plug 144. The patient cable 140 transmits an LED drive signal 252 (FIG. 2) from the monitor 160 to the sensor 110 and a resulting detector signal 254 (FIG. 2) from the sensor 110 to the monitor 160. The monitor 160 processes the 55 detector signal 254 (FIG. 2) to provide, typically, a numerical readout of the patient's oxygen saturation, a numerical readout of pulse rate, and an audible indicator or "beep" that occurs in response to each arterial pulse.

As shown in FIG. 2, the sensor 110 has both red and 60 infrared LED emitters 212 and a photodiode detector 214. The monitor 160 has a sensor interface 271, a signal processor 273, a controller 275, output drivers 276, a display and audible indicator 278, and a keypad 279. The monitor 160 determines oxygen saturation by computing the differ- 65 ential absorption by arterial blood of the two wavelengths emitted by the sensor emitters 212, as is well-known in the

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art. The sensor interface 271 provides LED drive current 252 which alternately activates the red and IR LED emitters 212. The photodiode detector 214 generates a signal 254 corresponding to the red and infrared light energy attenuated from transmission through the patient finger 10 (FIG. 1). The sensor interface 271 also has input circuitry for amplification, filtering and digitization of the detector signal 254. The signal processor 273 calculates a ratio of detected red and infrared intensities, and an arterial oxygen saturation value is empirically determined based on that ratio. The controller 275 provides hardware and software interfaces for managing the display and audible indicator 278 and keypad 279. The display and audible indicator 278 shows the computed oxygen status, as described above, and provides the pulse beep as well as alarms indicating oxygen desaturation events. The keypad 279 provides a user interface for setting alarm thresholds, alarm enablement, and display options, to name a few.

SUMMARY OF THE INVENTION

Conventional physiological measurement systems are limited by the patient cable connection between sensor and monitor. A patient must be located in the immediate vicinity of the monitor. Also, patient relocation requires either disconnection of monitoring equipment and a corresponding loss of measurements or an awkward simultaneous movement of patient equipment and cables. Various devices have been proposed or implemented to provide wireless communication links between sensors and monitors, freeing patients from the patient cable tether. These devices, however, are incapable of working with the large installed base of existing monitors and sensors, requiring caregivers and medical institutions to suffer expensive wireless upgrades. It is desirable, therefore, to provide a communications adapter that is plug-compatible both with existing sensors and monitors and that implements a wireless link replacement for the patient cable.

An aspect of a physiological measurement communica-Patient vital sign monitoring may include measurements 40 tions adapter comprises a sensor interface configured to receive a sensor signal. A transmitter modulates a first baseband signal responsive to the sensor signal so as to generate a transmit signal. A receiver demodulates a receive signal corresponding to the transmit signal so as to generate a second baseband signal corresponding to the first baseband signal. Further, a monitor interface is configured to communicate a waveform responsive to the second baseband signal to a sensor port of a monitor. The waveform is adapted to the monitor so that measurements derived by the monitor from the waveform are generally equivalent to measurements derivable from the sensor signal. The communications adapter may further comprise a signal processor having an input in communications with the sensor interface, where the signal processor is operable to derive a parameter responsive to the sensor signal and where the first baseband signal is responsive to the parameter. The parameter may correspond to at least one of a measured oxygen saturation and a pulse rate.

One embodiment may further comprise a waveform generator that synthesizes the waveform from a predetermined shape. The waveform generator synthesizes the waveform at a frequency adjusted to be generally equivalent to the pulse rate. The waveform may have a first amplitude and a second amplitude, and the waveform generator may be configured to adjusted the amplitudes so that measurements derived by the monitor are generally equivalent to a measured oxygen saturation.

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In another embodiment, the sensor interface is operable on the sensor signal to provide a plethysmograph signal output, where the first baseband signal is responsive to the plethysmograph signal. This embodiment may further comprise a waveform modulator that modifies a decoded signal responsive to the second baseband signal to provide the waveform. The waveform modulator may comprise a demodulator that separates a first signal and a second signal from the decoded signal, an amplifier that adjusts amplitudes of the first and second signals to generate a first adjusted signal and a second adjusted signal, and a modulator that combines the first and second adjusted signals into the waveform. The amplitudes of the first and second signals may be responsive to predetermined calibration data for the sensor and the monitor.

An aspect of a physiological measurement communications adapter method comprises the steps of inputting a sensor signal at a patient location, communicating patient data derived from the sensor signal between the patient location and a monitor location, constructing a waveform at the monitor location responsive to the sensor signal, and 20 providing the waveform to a monitor via a sensor port. The waveform is constructed so that the monitor calculates a parameter generally equivalent to a measurement derivable from the sensor signal.

In one embodiment, the communicating step may com- 25 prise the substeps of deriving a conditioned signal from the sensor signal, calculating a parameter signal from the conditioned signal, and transmitting the parameter signal from the patient location to the monitor location. The constructing step may comprise the substep of synthesizing the waveform 30 from the parameter signal. In an alternative embodiment, the communicating step may comprise the substeps of deriving a conditioned signal from said sensor signal and transmitting the conditioned signal from the patient location to the monitor location. The constructing step may comprise the 35 substeps of demodulating the conditioned signal and remodulating the conditioned signal to generate the waveform. The providing step may comprise the substeps of inputting a monitor signal from an LED drive output of the sensor port, modulating the waveform in response to the monitor 40 signal, and outputting the waveform on a detector input of the sensor port.

Another aspect of a physiological measurement communications adapter comprises a sensor interface means for inputting a sensor signal and outputting a conditioned signal, 45 a transmitter means for sending data responsive to the sensor signal, and a receiver means for receiving the data. The communications adapter further comprises a waveform processor means for constructing a waveform from the data so that measurements derived by a monitor from the waveform 50 are generally equivalent to measurements derivable from the sensor signal, and a monitor interface means for communicating the waveform to a sensor port of the monitor. The communications adapter may further comprise a signal processor means for deriving a parameter signal from the 55 conditioned signal, where the data comprises the parameter signal. The waveform processor means may comprise a means for synthesizing the waveform from the parameter signal. The data may comprise the conditioned signal, and the waveform processor means may comprise a means for 60 modulating the conditioned signal in response to the monitor.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is an illustration of a prior art pulse oximetry system:

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FIG. 2 is a functional block diagram of a prior art pulse oximetry system;

FIG. 3 is an illustration of a physiological measurement communications adapter;

FIGS. 4A-B are illustrations of communications adapter sensor modules:

FIGS. **5**A-C are illustrations of communications adapter monitor modules;

FIG. 6 is a functional block diagram of a communications adapter sensor module;

FIG. 7 is a functional block diagram of a communications adapter monitor module;

FIG. 8 is a functional block diagram of a sensor module configured to transmit measured pulse oximeter parameters;

FIG. 9 is a functional block diagram of a monitor module configured to received measured pulse oximeter parameters;

FIG. 10 is a functional block diagram of a sensor module configured to transmit a plethysmograph;

FIG. 11 is a functional block diagram of a monitor module configured to receive a plethysmograph;

FIG. 12 is a functional block diagram of a waveform modulator:

FIG. 13 is a functional block diagram of a sensor module configured for multiple sensors; and

FIG. 14 is a functional block diagram of a monitor module configured for multiple sensors.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Overview

FIG. 3 illustrates one embodiment of a communications adapter. FIGS. 4-5 illustrate physical configurations for a communications adapter. In particular, FIGS. 4A-B illustrate sensor module configurations and FIGS. 5A-C illustrate monitor module configurations. FIGS. 6-14 illustrate communications adapter functions. In particular, FIGS. 6-7 illustrate general functions for a sensor module and a monitor module, respectively. FIGS. 8-9 functionally illustrate a communications adapter where derived pulse oximetry parameters, such as saturation and pulse rate are transmitted between a sensor module and a monitor module. Also, FIGS. 10-12 functionally illustrate a communications adapter where a plethysmograph is transmitted between a sensor module and a monitor module. FIGS. 13-14 functionally illustrate a multiple-parameter communications adapter.

FIG. 3 illustrates a communications adapter 300 having a sensor module 400 and a monitor module 500. The communications adapter 300 communicates patient data derived from a sensor 310 between the sensor module 400, which is located proximate a patient 20 and the monitor module 500, which is located proximate a monitor 360. A wireless link 340 is provided between the sensor module 400 and the monitor module 500, replacing the conventional patient cable, such as a pulse oximetry patient cable 140 (FIG. 1). Advantageously, the sensor module 400 is plug-compatible with a conventional sensor 310. In particular, the sensor connector 318 connects to the sensor module 400 in a similar manner as to a patient cable. Further, the sensor module 400 outputs a drive signal to the sensor 310 and inputs a sensor signal from the sensor 310 in an equivalent manner as a conventional monitor 360. The sensor module 400 may be battery powered or externally powered. External power may be for recharging internal batteries or for powering the sensor module during operation or both.

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As shown in FIG. 3, the monitor module 500 is advantageously plug-compatible with a conventional monitor 360. In particular, the monitor's sensor port 362 connects to the monitor module 500 in a similar manner as to a patient cable, such as a pulse oximetry patient cable 140 (FIG. 1). Further, 5 the monitor module 500 inputs a drive signal from the monitor 360 and outputs a corresponding sensor signal to the monitor 360 in an equivalent manner as a conventional sensor 310. As such, the combination sensor module 400 and monitor module 500 provide a plug-compatible wireless replacement for a patient cable, adapting an existing wired physiological measurement system into a wireless physiological measurement system. The monitor module 500 may be battery powered, powered from the monitor, such as by tapping current from a monitor's LED drive, or externally 15 powered from an independent AC or DC power source.

Although a communications adapter 300 is described herein with respect to a pulse oximetry sensor and monitor, one of ordinary skill in the art will recognize that a communications adapter may provide a plug-compatible wireless replace for a patient cable that connects any physiological sensor and corresponding monitor. For example, a communications adapter 300 may be applied to a biopotential sensor, a non-invasive blood pressure (NIBP) sensor, a respiratory rate sensor, a glucose sensor and the corresponding monitors, to name a few.

Sensor Module Physical Configurations

FIGS. 4A-B illustrate physical embodiments of a sensor module 400. FIG. 4A illustrates a wrist-mounted module 410 having a wrist strap 411, a case 412 and an auxiliary 30 cable 420. The case 412 contains the sensor module electronics, which are functionally described with respect to FIG. 6, below. The case 412 is mounted to the wrist strap 411, which attaches the wrist-mounted module 410 to a patient 20. The auxiliary cable 420 mates to a sensor 35 connector 318 and a module connector 414, providing a wired link between a conventional sensor 310 and the wrist-mounted module 410. Alternatively, the auxiliary cable 420 is directly wired to the sensor module 400. The wrist-mounted module 410 may have a display 415 that 40 shows sensor measurements, module status and other visual indicators, such as monitor status. The wrist-mounted module 410 may also have keys (not shown) or other input mechanisms to control its operational mode and characteristics. In an alternative embodiment, the sensor 310 may 45 have a tail (not shown) that connects directly to the wristmounted module 410, eliminating the auxiliary cable 420.

FIG. 4B illustrates a clip-on module 460 having a clip 461, a case 462 and an auxiliary cable 470. The clip 461 attaches the clip-on module 460 to patient clothing or 50 objects near a patient 20, such as a bed frame. The auxiliary cable 470 mates to the sensor connector 318 and functions as for the auxiliary cable 420 (FIG. 4A) of the wrist-mounted module 410 (FIG. 4A), described above. The clip-on module 460 may have a display 463 and keys 464 as 55 for the wrist-mounted module 410 (FIG. 4A). Either the wrist-mounted module 410 or the clip-on module 460 may have other input or output ports (not shown) that download software, configure the module, or provide a wired connection to other measurement instruments or computing 60 devices, to name a few examples.

Monitor Module Physical Configurations

FIGS. 5A-C illustrate physical embodiments of a monitor module 500. FIG. 5A illustrates a direct-connect module 510 having a case 512 and an integrated monitor connector 514. 65 The case 512 contains the monitor module electronics, which are functionally described with respect to FIG. 7,

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below. The monitor connector **514** mimics that of the monitor end of a patient cable, such as a pulse oximetry patient cable **140** (FIG. 1), and electrically and mechanically connects the monitor module **510** to the monitor **360** via the monitor's sensor port **362**.

FIG. 5B illustrates a cable-connect module 540 having a case 542 and an auxiliary cable 550. The case 542 functions as for the direct-connect module 510 (FIG. 5A), described above. Instead of directly plugging into the monitor 360, the cable-connect module 540 utilizes the auxiliary cable 550, which mimics the monitor end of a patient cable, such as a pulse oximetry patient cable 140 (FIG. 1), and electrically connects the cable-connect module 540 to the monitor sensor port 362.

FIG. 5C illustrates a plug-in module 570 having a plug-in case 572 and an auxiliary cable 580. The plug-in case 572 is mechanically compatible with the plug-in chassis of a multiparameter monitor 370 and may or may not electrically connect to the chassis backplane. The auxiliary cable 580 mimics a patient cable and electrically connects the plug-in module 570 to the sensor port 372 of another plug-in device. A direct-connect module 510 (FIG. 5A) or a cable-connect module 540 (FIG. 5B) may also be used with a multiparameter monitor 370.

In a multiparameter embodiment, such as described with respect to FIGS. 13-14, below, a monitor module 500 may connect to multiple plug-in devices of a multiparameter monitor 370. For example, a cable-connect module 540 (FIG. 5B) may have multiple auxiliary cables 550 (FIG. 5B) that connect to multiple plug-in devices installed within a multiparameter monitor chassis. Similarly, a plug-in module 570 may have one or more auxiliary cables 580 with multiple connectors for attaching to the sensor ports 372 of multiple plug-in devices.

Communications Adapter Functions

FIGS. 6-7 illustrate functional embodiments of a communications adapter. FIG. 6 illustrates a sensor module 400 having a sensor interface 610, a signal processor 630, an encoder 640, a transmitter 650 and a transmitting antenna 670. A physiological sensor 310 provides an input sensor signal 612 at the sensor connector 318. Depending on the sensor 310, the sensor module 400 may provide one or more drive signals 618 to the sensor 310. The sensor interface 610 inputs the sensor signal 612 and outputs a conditioned signal 614. The conditioned signal 614 may be coupled to the transmitter 650 or further processed by a signal processor 630. If the sensor module configuration utilizes a signal processor 630, it derives a parameter signal 632 responsive to the sensor signal 612, which is then coupled to the transmitter 650. Regardless, the transmitter 650 inputs a baseband signal 642 that is responsive to the sensor signal **612**. The transmitter **650** modulates the baseband signal **642** with a carrier to generate a transmit signal 654. The transmit signal 654 may be derived by various amplitude, frequency or phase modulation schemes, as is well known in the art. The transmit signal 654 is coupled to the transmit antenna 670, which provides wireless communications to a corresponding receive antenna 770 (FIG. 7), as described below.

As shown in FIG. 6, the sensor interface 610 conditions and digitizes the sensor signal 612 to generate the conditioned signal 614. Sensor signal conditioning may be performed in the analog domain or digital domain or both and may include amplification and filtering in the analog domain and filtering, buffering and data rate modification in the digital domain, to name a few. The resulting conditioned signal 614 is responsive to the sensor signal 612 and may be used to calculate or derive a parameter signal 632.

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Further shown in FIG. 6, the signal processor 630 performs signal processing on the conditioned signal 614 to generate the parameter signal 632. The signal processing may include buffering, digital filtering, smoothing, averaging, adaptive filtering and frequency transforms to name a 5 few. The resulting parameter signal 632 may be a measurement calculated or derived from the conditioned signal, such as oxygen saturation, pulse rate, blood glucose, blood pressure and EKG to name a few. Also, the parameter signal 632 may be an intermediate result from which the above-stated 10 measurements may be calculated or derived.

As described above, the sensor interface 610 performs mixed analog and digital pre-processing of an analog sensor signal and provides a digital output signal to the signal processor 630. The signal processor 630 then performs 15 digital post-processing of the front-end processor output. In alternative embodiments, the input sensor signal 612 and the output conditioned signal 614 may be either analog or digital, the front-end processing may be purely analog or purely digital, and the back-end processing may be purely 20 analog or mixed analog or digital.

In addition, FIG. 6 shows an encoder 640, which translates a digital word or serial bit stream, for example, into the baseband signal 642, as is well-known in the art. The baseband signal 642 comprises the symbol stream that 25 drives the transmit signal 654 modulation, and may be a single signal or multiple related signal components, such as in-phase and quadrature signals. The encoder 640 may include data compression and redundancy, also well-known in the art.

FIG. 7 illustrates a monitor module 500 having a receive antenna 770, a receiver 710, a decoder 720, a waveform processor 730 and a monitor interface 750. A receive signal 712 is coupled from the receive antenna 770, which provides wireless communications to a corresponding transmit 35 antenna 670 (FIG. 6), as described above. The receiver 710 inputs the receive signal 712, which corresponds to the transmit signal 654 (FIG. 6). The receiver 710 demodulates the receive signal to generate a baseband signal 714. The decoder 720 translates the symbols of the demodulated 40 baseband signal 714 into a decoded signal 724, such as a digital word stream or bit stream. The waveform processor 730 inputs the decoded signal 724 and generates a constructed signal 732. The monitor interface 750 is configured to communicate the constructed signal 732 to a sensor port 45 362 of a monitor 360. The monitor 360 may output a sensor drive signal 754, which the monitor interface 750 inputs to the waveform processor 730 as a monitor drive signal 734. The waveform processor 730 may utilize the monitor drive signal 734 to generate the constructed signal 732. The 50 monitor interface 750 may also provide characterization information 758 to the waveform processor 730, relating to the monitor 360, the sensor 310 or both, that the waveform processor 730 utilizes to generate the constructed signal 732.

The constructed signal **732** is adapted to the monitor **360** 55 so that measurements derived by the monitor **360** from the constructed signal **732** are generally equivalent to measurements derivable from the sensor signal **612** (FIG. **6**). Note that the sensor **310** (FIG. **6**) may or may not be directly compatible with the monitor **360**. If the sensor **310** (FIG. **6**) 60 is compatible with the monitor **360**, the constructed signal **732** is generated so that measurements derived by the monitor **360** from the constructed signal **732** are generally equivalent (within clinical significance) with those derivable directly from the sensor signal **612** (FIG. **6**). If the sensor 65 **310** (FIG. **6**) is not compatible with the monitor **360**, the constructed signal **732** is generated so that measurements

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derived by the monitor 360 from the constructed signal 732 are generally equivalent to those derivable directly from the sensor signal 612 (FIG. 6) using a compatible monitor. Wireless Pulse Oximetry

FIGS. **8-11** illustrate pulse oximeter embodiments of a communications adapter. FIGS. **8-9** illustrate a sensor module and a monitor module, respectively, configured to communicate measured pulse oximeter parameters. FIG. **10-11** illustrate a sensor module and a monitor module, respectively, configured to communicate a plethysmograph signal. Parameter Transmission

FIG. 8 illustrates a pulse oximetry sensor module 800 having a sensor interface 810, signal processor 830, encoder 840, transmitter 850, transmitting antenna 870 and controller 890. The sensor interface 810, signal processor 830 and controller 890 function as described with respect to FIG. 2, above. The sensor interface 810 communicates with a standard pulse oximetry sensor 310, providing an LED drive signal 818 to the LED emitters 312 and receiving a sensor signal 812 from the detector 314 in response. The sensor interface 810 provides front-end processing of the sensor signal 812, also described above, providing a plethysmograph signal 814 to the signal processor 830. The signal processor 830 then derives a parameter signal 832 that comprises a real time measurement of oxygen saturation and pulse rate. The parameter signal 832 may include other parameters, such as measurements of perfusion index and signal quality. In one embodiment, the signal processor is an MS-5 or MS-7 board available from Masimo Corporation, Irvine. Calif.

As shown in FIG. 8, the encoder 840, the transmitter 850 and the transmitting antenna 870 function as described with respect to FIG. 6, above. For example, the parameter signal 832 may be a digital word stream that is serialized into a bit stream and encoded into a baseband signal 842. The baseband signal 842 may be, for example, two bit symbols that drive a quadrature phase shift keyed (QPSK) modulator in the transmitter 850. Other encodings and modulations are also applicable, as described above. The transmitter 850 inputs the baseband signal 842 and generates a transmit signal 854 that is a modulated carrier having a frequency suitable for short-range transmission, such as within a hospital room, doctor's office, emergency vehicle or critical care ward, to name a few. The transmit signal 854 is coupled to the transmit antenna 870, which provides wireless communications to a corresponding receive antenna 970 (FIG. 9), as described below.

FIG. 9 illustrates a monitor module 900 having a receive antenna 970, a receiver 910, a decoder 920, a waveform generator 930 and an interface cable 950. The receive antenna 970, receiver 910 and decoder 920 function as described with respect to FIG. 7, above. In particular, the receive signal 912 is coupled from the receive antenna 970, which provides wireless communications to a corresponding transmit antenna 870 (FIG. 8). The receiver 910 inputs the receive signal 912, which corresponds to the transmit signal 854 (FIG. 8). The receiver 810 demodulates the receive signal 912 to generate a baseband signal 914. Not accounting for transmission errors, the baseband signal 914 corresponds to the sensor module baseband signal 842 (FIG. 8), for example a symbol stream of two bits each. The decoder 920 assembles the baseband signal 914 into a parameter signal 924, which, for example, may be a sequence of digital words corresponding to oxygen saturation and pulse rate. Again, not accounting for transmission errors, the monitor

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module parameter signal **924** corresponds to the sensor module parameter signal **832** (FIG. **8**), derived by the signal processor **830** (FIG. **8**).

Also shown in FIG. 9, the waveform generator 930 is a particular embodiment of the waveform processor 730 (FIG. 5 7) described above. The waveform generator 930 generates a synthesized waveform 932 that the pulse oximeter monitor 360 can process to calculate SpO2 and pulse rate values or exception messages. In the present embodiment, the waveform generator output does not reflect a physiological waveform. In particular, the synthesized waveform is not physiological data from the sensor module 800, but is a waveform synthesized from predetermined stored waveform data to cause the monitor 360 to calculate oxygen saturation and pulse rate equivalent to or generally equivalent (within 15 clinical significance) to that calculated by the signal processor 830 (FIG. 8). The actual intensity signal from the patient received by the detector 314 (FIG. 8) is not provided to the monitor 360 in the present embodiment. Indeed, the waveform provided to the monitor 360 will usually not resemble 20 a plethysmographic waveform or other physiological data from the patient to whom the sensor module 800 (FIG. 8) is

The synthesized waveform 932 is modulated according to the drive signal input 934. That is, the pulse oximeter 25 monitor 360 expects to receive a red and IR modulated intensity signal originating from a detector, as described with respect to FIGS. 1-2, above. The waveform generator 930 generates the synthesized waveform 932 with a predetermined shape, such as a triangular or sawtooth waveform 30 stored in waveform generator memory or derived by a waveform generator algorithm. The waveform is modulated synchronously with the drive input 934 with first and second amplitudes that are processed in the monitor 360 as red and IR portions of a sensor signal. The frequency and the first 35 and second amplitudes are adjusted so that pulse rate and oxygen saturation measurements derived by the pulse oximeter monitor 360 are generally equivalent to the parameter measurements derived by the signal processor 830 (FIG. 8), as described above. One embodiment of a waveform gen- 40 erator 930 is described in U.S. Patent Application No. 60/117,097 entitled "Universal/Upgrading Pulse Oximeter," assigned to Masimo Corporation, Irvine, Calif. and incorporated by reference herein. Although the waveform generator 930 is described above as synthesizing a waveform 45 that does not resemble a physiological signal, one of ordinary skill will recognize that another embodiment of the waveform generator 930 could incorporate, for example, a plethysmograph simulator or other physiological signal simulator.

Further shown in FIG. 9, the interface cable 950 functions in a manner similar to the monitor interface 750 (FIG. 7) described above. The interface cable 950 is configured to communicate the synthesized waveform 932 to the monitor **360** sensor port and to communicate the sensor drive signal 55 934 to the waveform generator 930. The interface cable 950 may include a ROM 960 that contains monitor and sensor characterization data. The ROM 960 is read by the waveform generator 930 so that the synthesized waveform 932 is adapted to a particular monitor 360. For example, the ROM 60 960 may contain calibration data of red/IR versus oxygen saturation, waveform amplitude and waveform shape information. An interface cable is described in U.S. Patent Application No. 60/117,092, referenced above. Monitorspecific SatShare™ brand interface cables are available 65 from Masimo Corporation, Irvine, Calif. In an alternative embodiment, such as a direct connect monitor module as

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illustrated in FIG. 5A, an interface cable 950 is not used and the ROM 960 may be incorporated within the monitor module 900 itself.

Plethysmograph Transmission

FIG. 10 illustrates another pulse oximetry sensor module 1000 having a sensor interface 1010, encoder 1040, transmitter 1050, transmitting antenna 1070 and controller 1090, which have the corresponding functions as those described with respect to FIG. 8, above. The encoder 1040, however, inputs a plethysmograph signal 1014 rather than oxygen saturation and pulse rate measurements 832 (FIG. 8). Thus, the sensor module 1000 according to this embodiment encodes and transmits a plethysmograph signal 1014 to a corresponding monitor module 1100 (FIG. 11) in contrast to derived physiological parameters, such as oxygen saturation and pulse rate. The plethysmograph signal 1014 is illustrated in FIG. 10 as being a direct output from the sensor interface 1010. In another embodiment, the sensor module 1000 incorporates a decimation processor, not shown, after the sensor interface 1010 so as to provide a plethysmograph signal 1014 having a reduced sample rate.

FIG. 11 illustrates another pulse oximetry monitor module 1100 having a receive antenna 1170, a receiver 1110, a decoder 1120 and an interface cable 1150, which have the corresponding functions as those described with respect to FIG. 9, above. This monitor module embodiment 1100, however, has a waveform modulator 1200 rather than a waveform generator 930 (FIG. 9), as described above. The waveform modulator 1200 inputs a plethysmograph signal from the decoder 1120 rather than oxygen saturation and pulse rate measurements, as described with respect to FIG. 9, above. Further, the waveform modulator 1200 provides an modulated waveform 1132 to the pulse oximeter monitor 360 rather than a synthesized waveform, as described with respect to FIG. 9. The modulated waveform 1132 is a plethysmographic waveform modulated according to the monitor drive signal input 1134. That is, the waveform modulator 1200 does not synthesize a waveform, but rather modifies the received plethysmograph signal 1124 to cause the monitor 360 to calculate oxygen saturation and pulse rate generally equivalent (within clinical significance) to that derivable by a compatible, calibrated pulse oximeter directly from the sensor signal 1012 (FIG. 10). The waveform modulator 1200 is described in further detail with respect to FIG. 12, below.

FIG. 12 shows a waveform modulator 1200 having a demodulator 1210, a red digital-to-analog converter (DAC) 1220, an IR DAC 1230, a red amplifier 1240, an IR amplifier 1250, a modulator 1260, a modulator control 1270, a lookup table (LUT) 1280 and a ratio calculator 1290. The waveform modulator 1200 demodulates red and IR plethysmographs ("pleths") from the decoder output 1124 into a separate red pleth 1222 and IR pleth 1232. The waveform modulator 1200 also adjusts the amplitudes of the pleths 1222, 1232 according to stored calibration curves for the sensor 310 (FIG. 10) and the monitor 360 (FIG. 11). Further, the waveform modulator 1200 re-modulates the adjusted red pleth 1242 and adjusted IR pleth 1252, generating a modulated waveform 1132 to the monitor 360 (FIG. 11).

As shown in FIG. 12, the demodulator 1210 performs the demodulation function described above, generating digital red and IR pleth signals 1212, 1214. The DACs 1220, 1230 convert the digital pleth signals 1212, 1214 to corresponding analog pleth signals 1222, 1232. The amplifiers 1240, 1250 have variable gain control inputs 1262, 1264 and perform the amplitude adjustment function described above, generating adjusted red and IR pleth signals 1242, 1252. The

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modulator 1260 performs the re-modulation function described above, combining the adjusted red and IR pleth signals 1242, 1252 according to a control signal 1272. The modulator control 1270 generates the control signal 1272 synchronously with the LED drive signal(s) 1134 from the 5 monitor 360.

Also shown in FIG. 12, the ratio calculator 1290 derives a red/IR ratio from the demodulator outputs 1212, 1214. The LUT 1280 stores empirical calibration data for the sensor 310 (FIG. 10). The LUT 1280 also downloads monitorspecific calibration data from the ROM 1160 (FIG. 11) via the ROM output 1158. From this calibration data, the LUT 1280 determines a desired red/IR ratio for the modulated waveform 1132 and generates red and IR gain outputs 1262, 1264 to the corresponding amplifiers 1240, 1250, accordingly. A desired red/IR ratio is one that allows the monitor 360 (FIG. 11) to derive oxygen saturation measurements from the modulated waveform 1132 that are generally equivalent to that derivable directly from the sensor signal 1012 (FIG. 10).

One of ordinary skill in the art will recognize that some of the signal processing functions described with respect to FIGS. **8-11** may be performed either within a sensor module or within a monitor module. Signal processing functions performed within a sensor module may advantageously 25 reduce the transmission bandwidth to a monitor module at a cost of increased sensor module size and power consumption. Likewise, signal processing functions performed within a monitor module may reduce sensor module size and power consumption at a cost of increase transmission bandwidth.

For example, a monitor module embodiment 900 (FIG. 9) described above receives measured pulse oximeter parameters, such as oxygen saturation and pulse rate, and generates a corresponding synthesized waveform. In that embodi- 35 ment, the oxygen saturation and pulse rate computations are performed within a sensor module 800 (FIG. 8). Another monitor module embodiment 1100 (FIG. 11), also described above, receives a plethysmograph waveform and generates a remodulated waveform. In that embodiment, minimal 40 signal processing is performed within a sensor module 1000 (FIG. 10). In yet another embodiment, not shown, a sensor module transmits a plethysmograph waveform or a decimated plethysmograph waveform having a reduced sample rate. A corresponding monitor module has a signal proces- 45 sor, such as described with respect to FIG. 8, in addition to a waveform generator, as described with respect to FIG. 9. The signal processor computes pulse oximeter parameters and the waveform generator generates a corresponding synthesized waveform, as described above. In this embodi- 50 ment, minimal signal processing is performed within the sensor module, and the monitor module functions are performed on the pulse oximeter parameters computed within the monitor module.

Wireless Multiple Parameter Measurements

FIGS. 13-14 illustrate a multiple parameter communications adapter. FIG. 13 illustrates a multiple parameter sensor module 1300 having sensor interfaces 1310, one or more signal processors 1330, a multiplexer and encoder 1340, a transmitter 1350, a transmitting antenna 1370 and a controller 1390. One or more physiological sensors 1301 provide input sensor signals 1312 to the sensor module 1300. Depending on the particular sensors 1301, the sensor module 1300 may provide one or more drive signals 1312 to the sensors 1301 as determined by the controller 1390. The 65 sensor interfaces 1310 input the sensor signals 1312 and output one or more conditioned signals 1314. The condi-

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tioned signals 1314 may be coupled to the transmitter 1350 or further processed by the signal processors 1330. If the sensor module configuration utilizes signal processors 1330, it derives multiple parameter signals 1332 responsive to the sensor signals 1312, which are then coupled to the transmitter 1350. Regardless, the transmitter 1350 inputs a baseband signal 1342 that is responsive to the sensor signals 1312. The transmitter 1350 modulates the baseband signal 1342 with a carrier to generate a transmit signal 1354, which is coupled to the transmit antenna 1370 and communicated to a corresponding receive antenna 1470 (FIG. 14), as described with respect to FIG. 6, above. Alternatively, there may be multiple baseband signals 1342, and the transmitter 1350 may transmit on multiple frequency channels, where each channel coveys data responsive to one or more of the sensor signals 1314.

As shown in FIG. 13, the sensor interface 1310 conditions and digitizes the sensor signals 1312 as described for a single sensor with respect to FIG. 6, above. The resulting 20 conditioned signals **1314** are responsive to the sensor signals 1312. The signal processors 1330 perform signal processing on the conditioned signals 1314 to derive parameter signals 1332, as described for a single conditioned signal with respect to FIG. 6, above. The parameter signals 1332 may be physiological measurements such as oxygen saturation, pulse rate, blood glucose, blood pressure, EKG, respiration rate and body temperature to name a few, or may be intermediate results from which the above-stated measurements may be calculated or derived. The multiplexer and encoder 1340 combines multiple digital word or serial bit streams into a single digital word or bit stream. The multiplexer and encoder also encodes the digital word or bit stream to generate the baseband signal 1342, as described with respect to FIG. 6, above.

FIG. 14 illustrates a multiple parameter monitor module 1400 having a receive antenna 1470, a receiver 1410, a demultiplexer and decoder 1420, one or more waveform processors 1430 and a monitor interface 1450. The receiver 1410 inputs and demodulates the receive signal 1412 corresponding to the transmit signal 1354 (FIG. 13) to generate a baseband signal **1414** as described with respect to FIG. **7**, above. The demultiplexer and decoder 1420 separates the symbol streams corresponding to the multiple conditioned signals 1314 (FIG. 13) and/or parameter signals 1332 (FIG. 13) and translates these symbol streams into multiple decoded signals 1422, as described for a single symbol stream with respect to FIG. 7, above. Alternatively, multiple frequency channels are received to generate multiple baseband signals, each of which are decoded to yield multiple decoded signals 1422. The waveform processors 1430 input the decoded signals 1422 and generate multiple constructed signals 1432, as described for a single decoded signal with respect to FIGS. 7-12, above. The monitor interface 1450 is configured to communicate the constructed signals 1432 to the sensor ports of a multiple parameter monitor 1401 or multiple single parameter monitors, in a manner similar to that for a single constructed signal, as described with respect to FIGS. 7-12, above. In particular, the constructed signals **1432** are adapted to the monitor **1401** so that measurements derived by the monitor 1401 from the constructed signals 1432 are generally equivalent to measurements derivable directly from the sensor signals 1312 (FIG. 13).

A physiological measurement communications adapter is described above with respect to wireless communications and, in particular, radio frequency communications. A sensor module and monitor module, however, may also communicate via wired communications, such as telephone, Internet

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or fiberoptic cable to name a few. Further, wireless communications can also utilize light frequencies, such as IR or laser to name a few.

A physiological measurement communications adapter has been disclosed in detail in connection with various 5 embodiments. These embodiments are disclosed by way of examples only. One of ordinary skill in the art will appreciate many variations and modifications of a physiological measurement communications adapter within the scope of the claims that follow.

What is claimed is:

- 1. An arm mountable portable patient monitoring device configured for both on-patient monitoring of parameter 15 measurements using one or more sensors operatively connected to the portable patient monitoring device and wireless transmission of parameter measurements, the portable patient monitoring device comprising:
 - a pulse oximetry sensor configured to be wrapped around 20 a digit of a patient, the pulse oximetry sensor including at least:
 - a light emitter configured to emit light into a tissue site of the digit of the patient;
 - a light detector configured output a signal responsive to 25 at least a portion of the emitted light after attenuation by tissue of the tissue site; and
 - a tail configured to electrically convey the signal;
 - a housing configured for, and having a size and shape configured for, mounting to a lower arm of the patient, 30 the housing including at least:
 - a display positioned on a front side of the housing that is opposite a back side of the housing, the display configured to show a status of the portable patient monitoring device and one or more parameter measurements so as to be viewable by a user;
 - a first sensor port positioned on a first side of the housing, the first side of the housing configured to face toward a hand having the digit of the patient under measurement, the first sensor port configured 40 to physically couple to the tail of the pulse oximetry sensor and to electrically receive the signal from the pulse oximetry sensor, wherein the first sensor port is positioned on the first side of the housing such that, when the tail is physically coupled to the first sensor 45 port, the tail extends from the first sensor port along an axis perpendicular to a face of the first side of the housing on which the first sensor port is positioned;
 - a second sensor port configured to receive information from an EKG sensor arrangement via a wired connection;
 - a third sensor port configured to receive information from a blood pressure sensor arrangement via a wired connection;
 - a rechargeable battery configured to power the portable 55 patient monitoring device including the pulse oximetry sensor;
 - one or more signal processing arrangements configured to:
 - receive the signal from the pulse oximetry sensor; derive, based on the signal, measurements of oxygen saturation and pulse rate; and
 - cause to be displayed, on the display, the measurements of oxygen saturation and pulse rate; and
 - a transmitter configured to:
 - wirelessly transmit a transmit signal indicative of the measurements of oxygen saturation and pulse rate

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- to a separate computing device configured to display the measurements of oxygen saturation and pulse rate; and
- a strap mountable to the back side of the housing, the strap configured to secure the housing to the lower arm of the patient.
- 2. The portable patient monitoring device of claim 1, wherein the tail comprises a cable extending from the pulse oximetry sensor to the first sensor port of the housing.
- 3. The portable patient monitoring device of claim 2, wherein the cable is removably coupled to the first sensor port of the housing, and wherein the digit of the patient is a thumb of the patient.
- **4**. The portable patient monitoring device of claim **1**, wherein the one or more signal processing arrangements comprise at least:
 - a sensor interface configured to:
 - receive the signal from the pulse oximetry sensor; and process the signal to generate a conditioned signal by at least one of:
 - amplification, filtering, analog to digital conversion, buffering, data rate modification, digital filtering, adaptive filtering, smoothing, averaging, or frequency transforming; and
 - a signal processor configured to:
 - receive the conditioned signal from the sensor interface:
 - derive, from the conditioned signal, the measurements of oxygen saturation and pulse rate; and
 - provide information indicative of the measurements of oxygen saturation and pulse rate to the transmitter.
- 5. The portable patient monitoring device of claim 4, wherein the sensor interface is further configured to:
 - provide the conditioned signal to the transmitter.
- **6**. The portable patient monitoring device of claim **1** further comprising:
 - an EKG sensor arrangement in electrical communication with the second sensor port of the housing;
 - wherein the one or more signal processing arrangements are further configured to:
 - receive the information from the EKG sensor arrangement at least in part via digital communication;
 - determine, from the information from the EKG sensor arrangement, an EKG measurement; and
 - cause to be displayed, on the display, the EKG measurement:
 - wherein the housing further includes a data combining arrangement configured to:
 - combine at least information indicative of the measurements of oxygen saturation, pulse rate, and EKG; and
 - wherein the transmitter is further configured to:
 - wirelessly transmit the transmit signal indicative of the measurements of oxygen saturation, pulse rate, and EKG to the separate computing device configured to display the measurements of oxygen saturation, pulse rate, and EKG.
- 7. The portable patient monitoring device of claim 6 further comprising:
 - a blood pressure sensor arrangement in electrical communication with the third sensor port of the housing;
 - wherein the one or more signal processing arrangements are further configured to:
 - receive the information from the blood pressure sensor arrangement at least in part via digital communication:

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- determine, from the information from the blood pressure sensor arrangement, a measurement of blood pressure; and
- cause to be displayed, on the display, the measurement of blood pressure;
- wherein the data combining arrangement is further configured to:
 - combine at least information indicative of the measurements of oxygen saturation, pulse rate, EKG, and blood pressure; and
- wherein the transmitter is further configured to:
- wirelessly transmit the transmit signal indicative of the measurements of oxygen saturation, pulse rate, EKG, and blood pressure to the separate computing device configured to display the measurements of oxygen 15 saturation, pulse rate, EKG, and blood pressure.
- **8**. The portable patient monitoring device of claim **7**, wherein the one or more signal processing arrangements are further configured to:
 - cause the measurements of oxygen saturation, pulse rate, 20 EKG, and blood pressure to all be displayed on the display of the portable patient monitoring device.
- **9**. The portable patient monitoring device of claim **7**, wherein:
 - the one or more signal processing arrangements are 25 further configured to:
 - receive the additional signals indicative of additional physiological parameters including at least one of: respiration rate or body temperature;
 - determine, from the additional signals, measurements 30 of the additional physiological parameters; and
 - cause to be displayed, on the display, the measurements of the additional physiological parameters;
 - wherein the data combining arrangement is further configured to:
 - combine at least information indicative of the measurements of oxygen saturation, pulse rate, EKG, blood pressure and the additional physiological parameters; and
 - wherein the transmitter is further configured to:
 - wirelessly transmit the transmit signal indicative of the measurements of oxygen saturation, pulse rate, EKG, blood pressure, and additional physiological parameters to the separate computing device configured to display the measurements of oxygen saturation, pulse rate, EKG, blood pressure, and additional physiological parameters.
- 10. The portable patient monitoring device of claim 9, wherein the one or more signal processing arrangements are further configured to:
 - cause the measurements of oxygen saturation, pulse rate, EKG, blood pressure, and additional physiological parameters to all be displayed on the display of the portable patient monitoring device.
- 11. The portable patient monitoring device of claim 10, 55 wherein the data combining arrangement is at least one of a multiplexer or an encoder.
- 12. The portable patient monitoring device of claim 1, wherein the measurements of oxygen saturation and pulse rate comprise real time measurements of oxygen saturation 60 and pulse rate.
- 13. The portable patient monitoring device of claim 1, wherein the one or more signal processing arrangements are further configured to determine, based on the signal, a measurement of signal quality.
- 14. The portable patient monitoring device of claim 1, wherein the housing further includes at least one or more

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- user input mechanisms configured to control an operational mode of the portable patient monitoring device in response to inputs from a user.
- 15. The portable patient monitoring device of claim 1, wherein the transmit signal indicative of the measurements of oxygen saturation and pulse rate comprises the derived measurements of oxygen saturation and pulse rate.
- 16. The portable patient monitoring device of claim 15, wherein the transmit signal indicative of the measurements of oxygen saturation and pulse rate further comprises raw data indicative of the signal from the pulse oximetry sensor.
- 17. An arm mountable portable patient monitoring device configured for both on-patient monitoring of parameter measurements using one or more sensors operatively connected to the portable patient monitoring device and wireless transmission of parameter measurements, the portable patient monitoring device comprising:
 - a pulse oximetry sensor configured to be wrapped around a digit of a patient, the pulse oximetry sensor including at least.
 - a light emitter configured to emit light into a tissue site of the digit of the patient; and
 - a light detector configured output a signal responsive to at least a portion of the emitted light after attenuation by tissue of the tissue site;
 - a housing configured to be mounted to an arm of the patient, the housing including at least:
 - a display positioned on a front side of the housing that is opposite a back side of the housing, the display configured to show a status of the portable patient monitoring device and one or more parameter measurements so as to be viewable by a user;
 - a first sensor port positioned on a first side of the housing, the first side of the housing having a face that is configured to face toward a hand having the digit of the patient under measurement, the first sensor port configured to electrically receive the signal from the pulse oximetry sensor via a wire extending from the pulse oximetry sensor to the first sensor port, wherein the wire extends from the first sensor port perpendicularly to the face of the first side of the housing;
 - second and third sensor ports configured to receive signals from two or more additional sensor arrangements via wired communications;
 - a rechargeable battery configured to power the portable patient monitoring device including the pulse oximetry sensor;
 - one or more signal processing arrangements configured to:
 - receive the signal from the pulse oximetry sensor;
 - cause to be displayed, on the display, measurements of oxygen saturation and pulse rate derived from the received signal; and
 - a transmitter configured to:
 - wirelessly transmit a transmit signal indicative of the measurements of oxygen saturation and pulse rate to a separate computing device configured to display the measurements of oxygen saturation and pulse rate; and
 - a strap mountable to the back side of the housing, the strap configured to secure the housing to the arm of the patient.
- 18. The portable patient monitoring device of claim 17 further comprising:

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- a second physiological sensor arrangement in electrical communication with the second sensor port of the housing, the second physiological sensor arrangement comprising at least one of: a blood pressure sensor arrangement, an EKG sensor arrangement, a respiration rate sensor arrangement, or a body temperature sensor arrangement;
- wherein the one or more signal processing arrangements are further configured to:
 - receive information from the second physiological sensor arrangement indicative of a physiological parameter of the patient, wherein the information from the second physiological sensor arrangement is at least partly digital; and
 - cause to be displayed, on the display one or more 15 additional parameter measurements, based on the information from the second physiological sensor arrangement, including measurements of at least one of: blood pressure, EKG, respiration rate, or body temperature:
- wherein the transmitter is further configured to wirelessly transmit the transmit signal indicative of the measurements of oxygen saturation and pulse rate, and the one or more additional parameter measurements, to the separate computing device configured to display the 25 measurements of oxygen saturation and pulse rate, and the one or more additional parameter measurements.
- 19. The portable patient monitoring device of claim 18 further comprising:
 - a third physiological sensor arrangement, different from the second physiological sensor arrangement, in electrical communication with the third sensor port of the housing, the third physiological sensor arrangement comprising at least one of: a blood pressure sensor arrangement, an EKG sensor arrangement, a respiration as rate sensor arrangement, or a body temperature sensor arrangement;
 - wherein the one or more signal processing arrangements are further configured to:
 - receive information from the third physiological sensor 40 arrangement indicative of a physiological parameter of the patient; and
 - cause to be displayed, on the display, the second one or more additional parameter measurements, based on information from the third physiological sensor 45 arrangement, including measurements of at least one of: blood pressure, EKG, respiration rate, or body temperature;
 - wherein the transmitter is further configured to wirelessly transmit the transmit signal indicative of the measurements of oxygen saturation and pulse rate, the one or more additional parameter measurements, and the second one or more additional parameter measurements, to the separate computing device configured to display the measurements of oxygen saturation and pulse rate, the 55 one or more additional parameter measurements, and the second one or more additional parameter measurements.
- 20. An arm mountable portable patient monitoring device configured for both on-patient monitoring of parameter 60 measurements using one or more sensors operatively connected to the portable patient monitoring device and wireless transmission of parameter measurements, the portable patient monitoring device comprising:
 - a pulse oximetry sensor configured to be wrapped around 65 a digit of a patient, the pulse oximetry sensor including at least:

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- a light emitter configured to emit light into a tissue site of the digit of the patient;
- a light detector configured output a first signal responsive to at least a portion of the emitted light after attenuation by tissue of the tissue site; and
- a cable extending from the pulse oximetry sensor and configured to electrically convey the first signal;
- a blood pressure sensor configured to output a second signal responsive to at least a blood pressure parameter of the patient;
- an additional sensor arrangement configured to output a third signal responsive to at least one additional physiological parameter of a patient other than blood pressure or oxygen saturation, the at least one additional physiological parameter including at least one of: temperature or respiration rate;
- a housing configured to be secured to a lower arm of the patient, the housing having a size and shape configured to be secured to the lower arm of the patient;
- a strap mountable to the back side of the housing, the strap configured to secure the housing to the lower arm of the patient;
- a display positioned on a front side of the housing that is opposite a back side of the housing, the display configured to show a status of the portable patient monitoring device and one or more parameter measurements so as to be viewable by a user, wherein the display is positioned centrally on the front side of the display and is sized such that the display spans most of a length of a shortest dimension of the front side of the housing, and wherein the front side of the housing comprises a single user interface and a bezel;
- one or more user input mechanisms configured to control an operational mode of the portable patient monitoring device in response to inputs from a user;
- a first sensor port positioned on a first side of the housing, wherein:
 - the first side of the housing is configured to face toward a hand having the digit of the patient under measurement when the housing is secured to the lower arm of the patient,
 - the first sensor port is configured to removably physically couple with the pulse oximetry sensor via the cable and to electrically receive the first signal from the pulse oximetry sensor,
 - the cable is configured to run from the first sensor port, at least part way down the arm of the patient, and to the digit of the patient to which the pulse oximetry sensor is configured to be wrapped around,
 - the first sensor port is positioned on the first side of the housing such that, when the cable is physically coupled to the first sensor port, the cable extends from the first sensor port along a path perpendicular to the first side of the housing on which the first sensor port is positioned,
 - the front side of the housing is raised from the strap and the lower arm of the patient to enable positioning of the first sensor port on the first side of the housing between the lower arm of the patient and the front side of the housing, and
 - a top of the first sensor port is located below the front of the housing;
- a second sensor port positioned on the housing and configured to provide electrical communication with the blood pressure sensor arrangement and to electrically receive second signal from the blood pressure sensor arrangement, wherein the second sensor port is

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- connectable to wire extending from the blood pressure sensor arrangement to provide the electrical communication with the blood pressure sensor arrangement;
- a third sensor port positioned on the housing and configured to provide electrical communication with the 5 additional sensor arrangement and to electrically receive the third signal from the additional sensor arrangement, wherein the third sensor port is connectable to wire extending from the additional sensor arrangement to provide the electrical communication 10 with the additional sensor arrangement;
- a rechargeable battery within the housing and configured to power the portable patient monitoring device including at least the pulse oximetry sensor such that the portable patient monitoring device is portable and 15 wearable by the patient;
- one or more signal processing arrangements within the housing and configured to:
 - receive the first signal from the pulse oximetry sensor via one or more sensor interfaces;
 - process the first signal from the pulse oximetry sensor to determine measurements of oxygen saturation and pulse rate, wherein the first signal is processed at least in part in the analog domain by at least one of: the one or more sensor interfaces, or the one or more 25 signal processing arrangements;
 - receive the second signal from the blood pressure sensor arrangement via the one or more sensor interfaces, wherein the second signal is processed at least in part in the digital domain by at least one of: 30 the one or more sensor interfaces, or the one or more signal processing arrangements;

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- receive the third signal from the additional sensor arrangement via the one or more sensor interfaces, wherein the third signal is processed at least in part in the digital domain by at least one of: the one or more sensor interfaces, or the one or more signal processing arrangements; and
- cause the measurements of oxygen saturation, pulse rate, blood pressure, and the at least one additional physiological parameter to all be displayed on the display of the portable patient monitoring device;
- a multiplexer within the housing and configured to combine at least information indicative of the measurements of oxygen saturation, pulse rate, blood pressure, and the at least one additional physiological parameter into a single digital word or bit stream;
- an encoder within the housing and configured to encode the single digital word or bit stream to generate a baseband signal; and
- a transmitter within the housing and configured to:
 modulate the baseband signal with a carrier to generate a transmit signal; and
- wirelessly transmit a transmit signal including the information indicating the measurements of oxygen saturation, pulse rate, blood pressure, and the at least one additional physiological parameter to a separate computing device configured to decode the transmit signal and display, on a remote display, the measurements of oxygen saturation, pulse rate, blood pressure, and the at least one additional physiological parameter.

* * * * *

Case 1:22-cv-01378-MN-JLH Document 175-1 Filed 07/14/23 Page 298 of 561 PageID #: 10877

UNITED STATES PATENT AND TRADEMARK OFFICE **CERTIFICATE OF CORRECTION**

PATENT NO. : 9,872,623 B2 Page 1 of 1

APPLICATION NO. : 15/494967

DATED : January 23, 2018

INVENTOR(S) : Ammar Al-Ali

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In Column 2 (page 11, item (56)) at Line 34, Under Other Publications, change "Aitkonhead" to --Aitkenhead--.

In Column 8 at Line 8, Change "FIG." to --FIGS.--.

In Column 13 at Line 25, In Claim 1, after "configured" insert --to--.

In Column 16 at Line 24 (approx.), In Claim 17, after "configured" insert --to--.

In Column 18 at Line 3, In Claim 20, after "configured" insert --to--.

Signed and Sealed this Twenty-ninth Day of May, 2018

Andrei Iancu

Director of the United States Patent and Trademark Office

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(54) ADAPTIVE ALARM SYSTEM

(71) Applicant: MASIMO Corporation, Irvine, CA (US)

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(21) Appl. No.: 15/881,602

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Related U.S. Patent Documents

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(51) **Int. Cl.**A61B 5/00 (2006.01)

A61B 5/1455 (2006.01)

(58) **Field of Classification Search**CPC ... A61B 5/746; A61B 5/1455; A61B 5/14552;
A61B 5/74

USPC 600/300, 301, 310, 322, 323, 324, 473, 600/476, 500, 508; 356/41, 573.1

See application file for complete search history.

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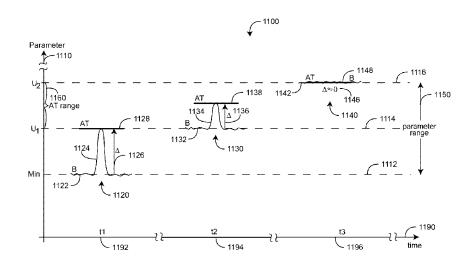
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(57) ABSTRACT

Systems and electronic processes for reducing electronic alarms in a medical patient monitoring system. For example, a system for reducing electronic alarms can include an optical sensor and one or more hardware processors in electronic communication with the optical sensor. The one or more hardware processors can be programmed to measure oxygen saturation values of a patient over a first period of time, determine if at least one oxygen saturation value obtained over the first period of time exceeds a first alarm threshold, determine whether a first alarm should be triggered based on the determination that the at least one oxygen saturation value obtained over the first period of time exceeds the first alarm threshold, determine a second alarm threshold to be applied during a second period of time subsequent to the first period of time, the second alarm threshold replacing the first alarm threshold.

17 Claims, 14 Drawing Sheets



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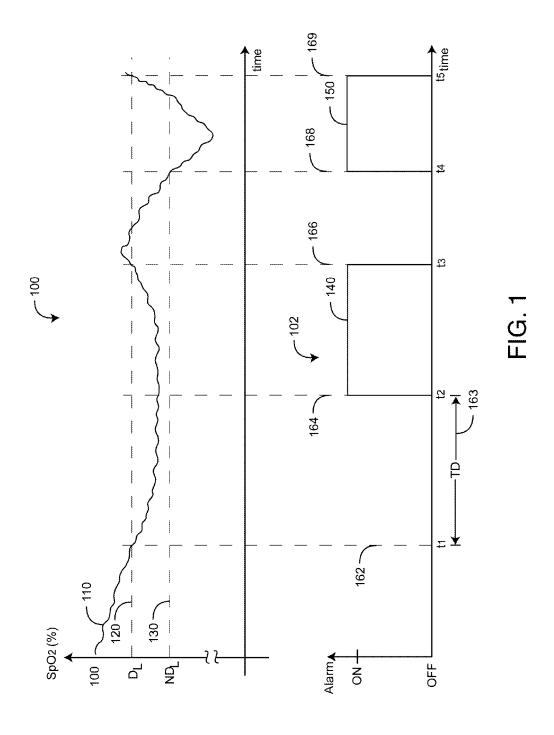
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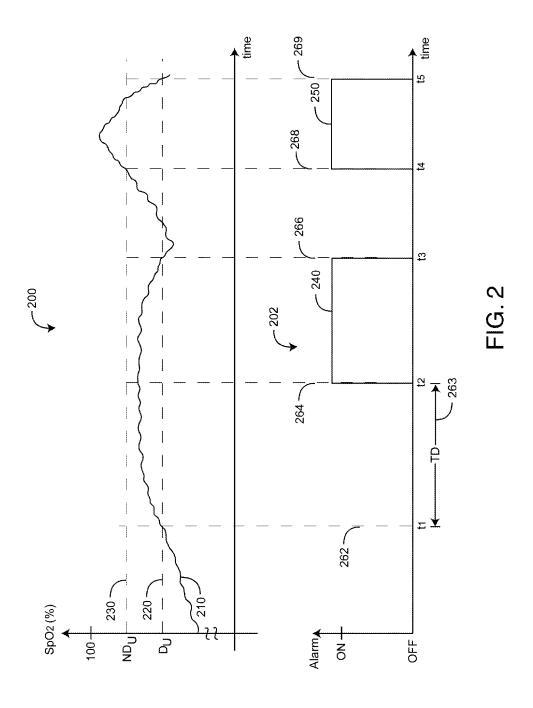
Feb. 5, 2019

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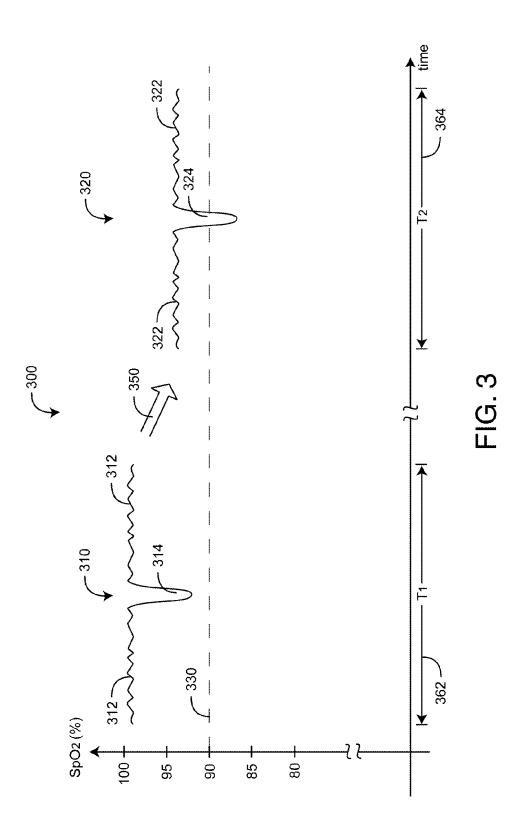
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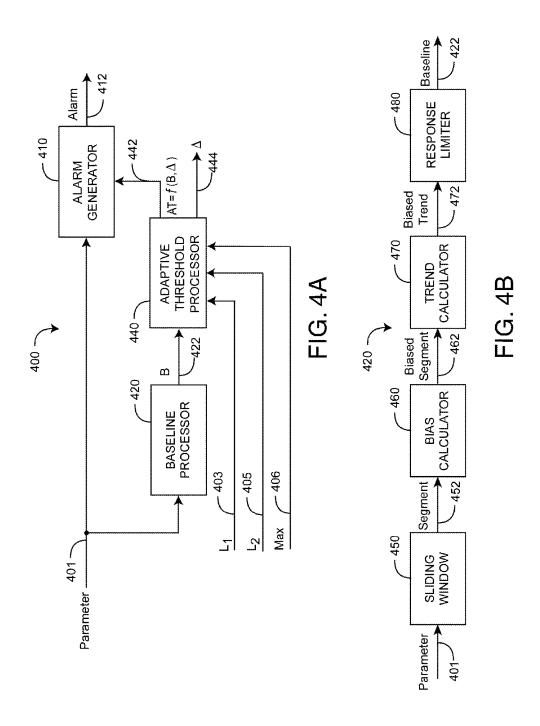
Feb. 5, 2019

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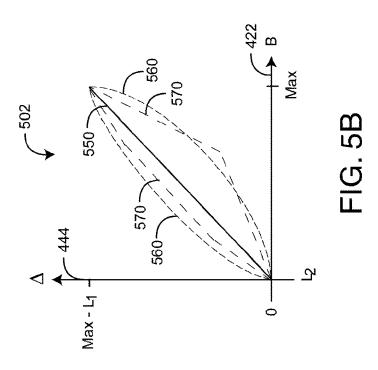
Feb. 5, 2019

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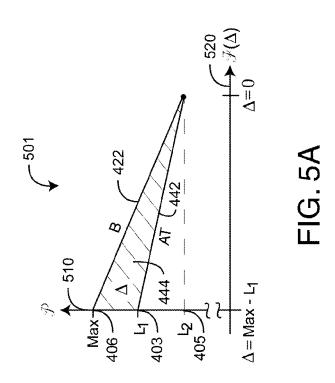
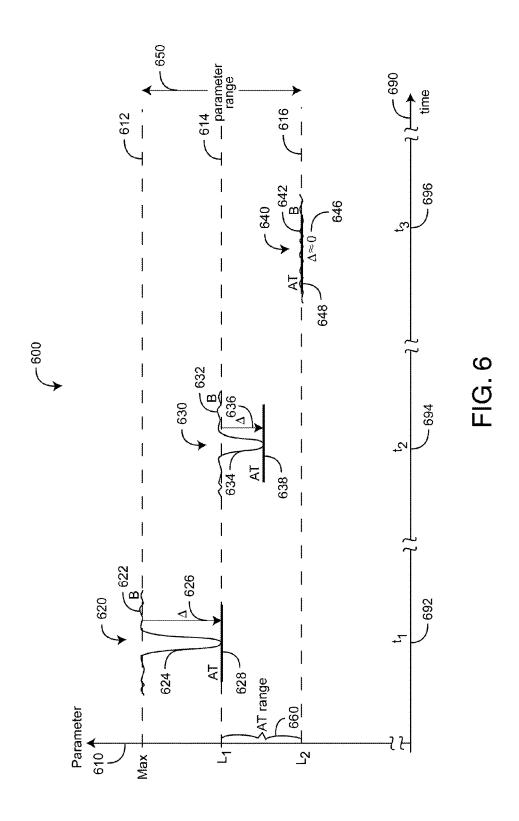


Exhibit 4 -127-

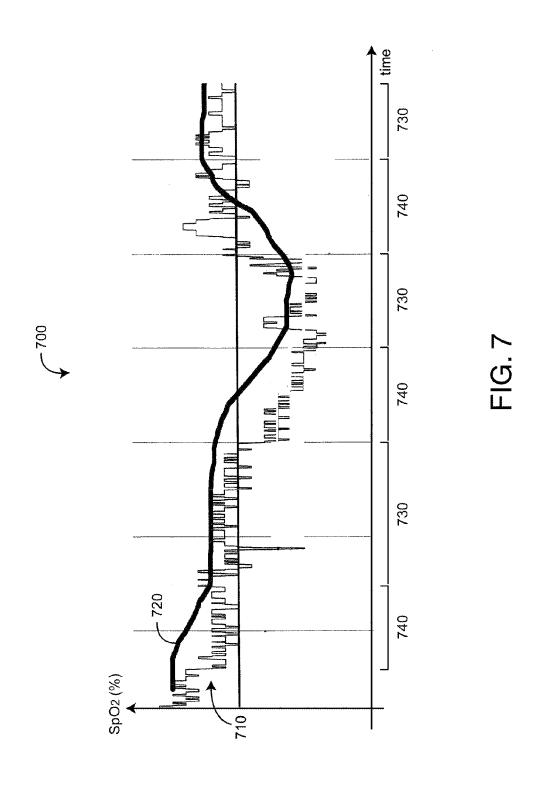
Feb. 5, 2019

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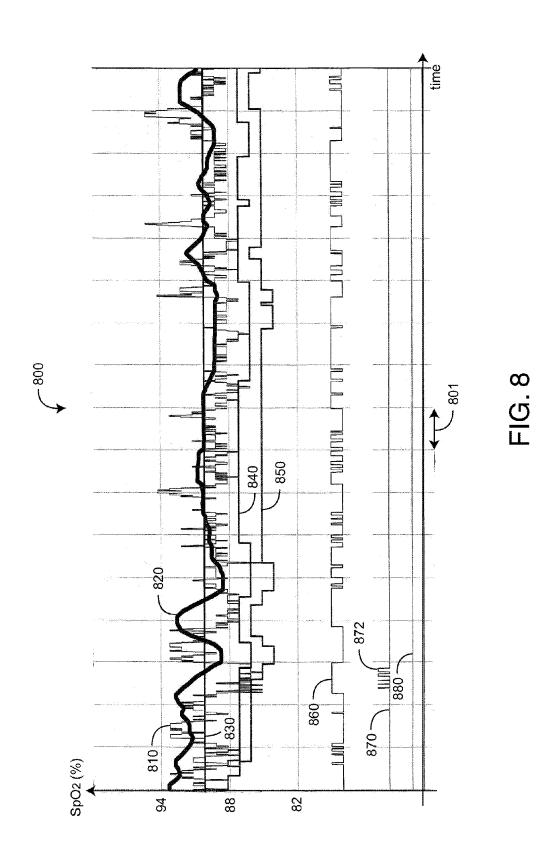
Feb. 5, 2019

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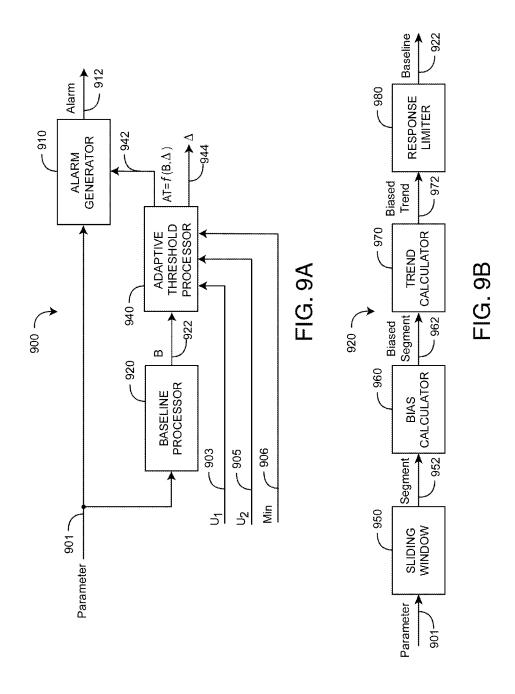
Feb. 5, 2019

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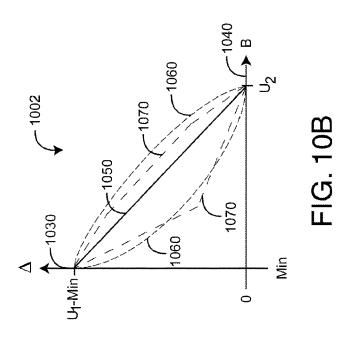
Feb. 5, 2019

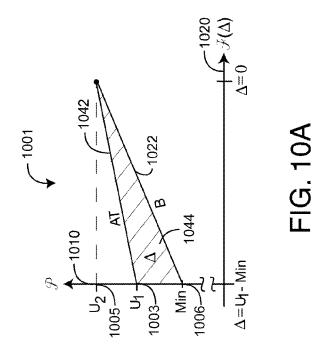
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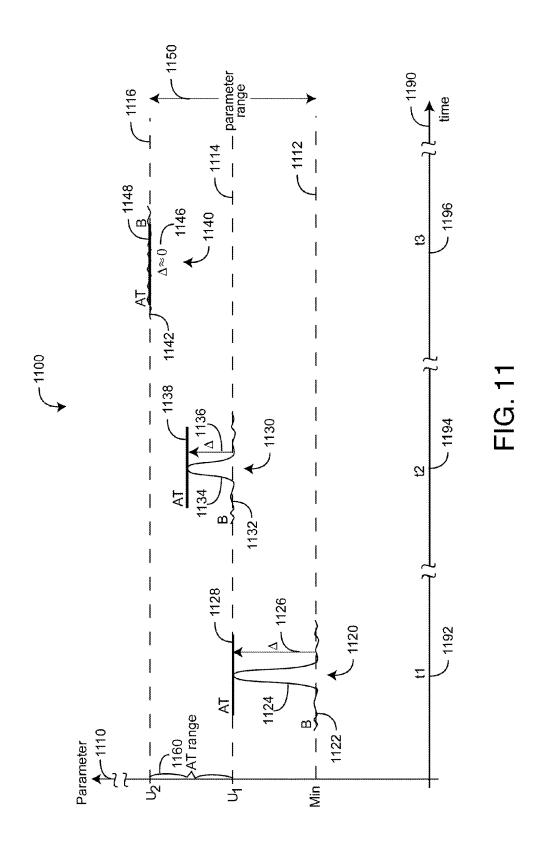
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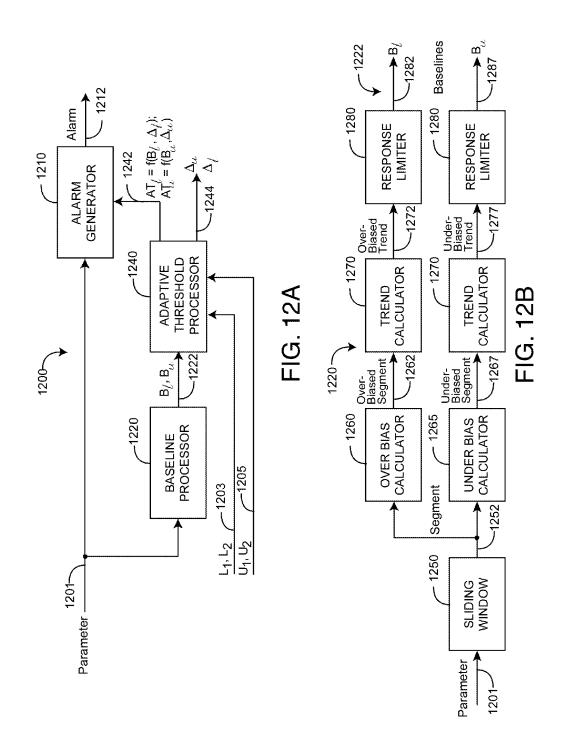
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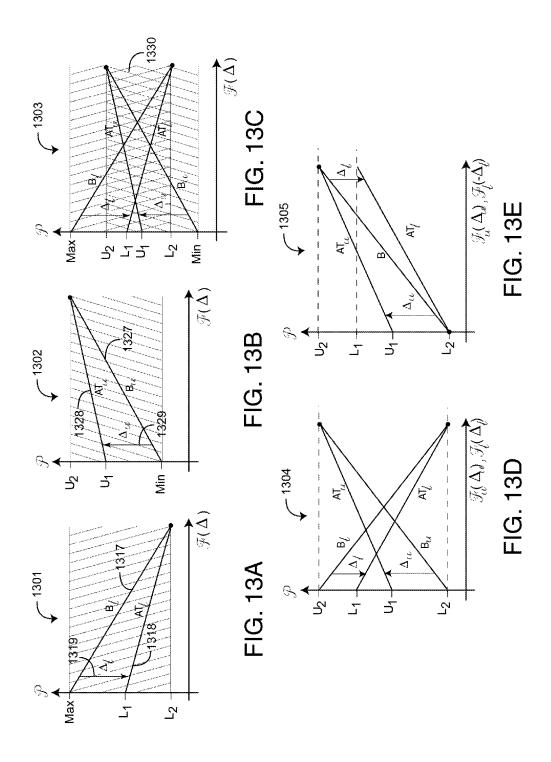
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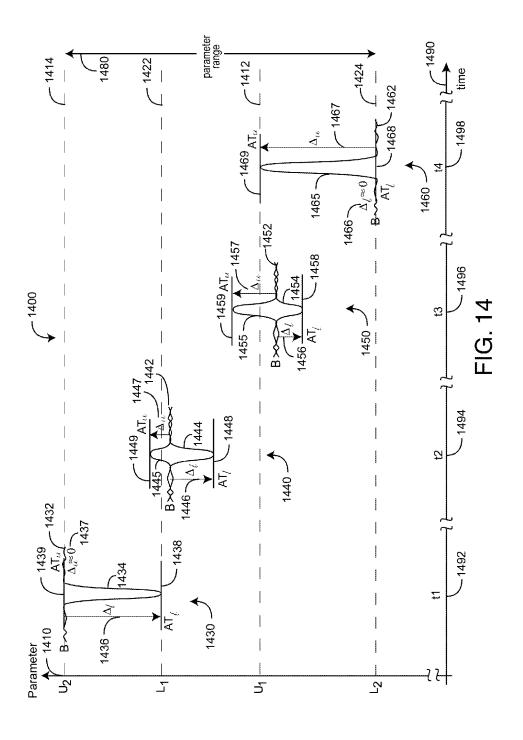
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1 ADAPTIVE ALARM SYSTEM

Matter enclosed in heavy brackets [] appears in the original patent but forms no part of this reissue specification; matter printed in italics indicates the additions made by reissue; a claim printed with strikethrough indicates that the claim was canceled, disclaimed, or held invalid by a prior post-patent action or proceeding.

PRIORITY CLAIM TO RELATED PROVISIONAL APPLICATIONS

The present application claims priority benefit under 35 U.S.C. §119(e) to *This is an application for reissue of U.S.* Pat. No. 9,775,570, issued on Oct. 3, 2017 and titled "Adaptive Alarm System," which is a continuation of U.S. patent application Ser. No. 13/037,184, filed Feb. 18, 2011 titled Adaptive Alarm System; which claims priority benefit under 35 U.S.C. § 119(e) to Provisional Patent Application Ser. No. 61/309,419, filed Mar. 1, 2010 titled Adaptive Threshold Alarm System; and U.S. Provisional Patent Application Ser. No. 61/328,630, filed Apr. 27, 2010 titled Adaptive Alarm System; all of the above-cited provisional patent applications are hereby incorporated by reference herein. More than one reissue application has been filed for the reissue of Pat. No. 9,775,570. The reissue applications are application Nos. 15/881,602 (the present application) and 16/184,908.

BACKGROUND OF THE INVENTION

Pulse oximetry systems for measuring constituents of circulating blood have gained rapid acceptance in a wide 35 variety of medical applications, including surgical wards, intensive care and neonatal units, general wards, home care, physical training, and virtually all types of monitoring scenarios. A pulse oximetry system generally includes an optical sensor applied to a patient, a monitor for processing 40 sensor signals and displaying results and a patient cable electrically interconnecting the sensor and the monitor. A pulse oximetry sensor has light emitting diodes (LEDs), typically one emitting a red wavelength and one emitting an infrared (IR) wavelength, and a photodiode detector. The 45 emitters and detector are typically attached to a finger, and the patient cable transmits drive signals to these emitters from the monitor. The emitters respond to the drive signals to transmit light into the fleshy fingertip tissue. The detector generates a signal responsive to the emitted light after 50 attenuation by pulsatile blood flow within the fingertip. The patient cable transmits the detector signal to the monitor, which processes the signal to provide a numerical readout of physiological parameters such as oxygen saturation (SpO₂) and pulse rate.

SUMMARY OF THE INVENTION

Conventional pulse oximetry assumes that arterial blood is the only pulsatile blood flow in the measurement site. 60 During patient motion, venous blood also moves, which causes errors in conventional pulse oximetry. Advanced pulse oximetry processes the venous blood signal so as to report true arterial oxygen saturation and pulse rate under conditions of patient movement. Advanced pulse oximetry 65 also functions under conditions of low perfusion (small signal amplitude), intense ambient light (artificial or sun-

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light) and electrosurgical instrument interference, which are scenarios where conventional pulse oximetry tends to fail.

Advanced pulse oximetry is described in at least U.S. Pat. Nos. 6,770,028; 6,658,276; 6,157,850; 6,002,952; 5,769,785 and 5,758,644, which are assigned to Masimo Corporation ("Masimo") of Irvine, Calif. and are incorporated by reference herein. Corresponding low noise optical sensors are disclosed in at least U.S. Pat. Nos. 6,985,764; 6,813,511; 6,792,300; 6,256,523; 6,088,607; 5,782,757 and 5,638,818, which are also assigned to Masimo and are also incorporated by reference herein. Advanced pulse oximetry systems including Masimo SET® low noise optical sensors and read through motion pulse oximetry monitors for measuring SpO₂, pulse rate (PR) and perfusion index (PI) are available from Masimo. Optical sensors include any of Masimo LNOP®, LNCS®, SofTouch™ and Blue™ adhesive or reusable sensors. Pulse oximetry monitors include any of Masimo Rad-8®, Rad-5®, Rad®-5v or SatShare® moni-

Advanced blood parameter measurement systems are described in at least U.S. Pat. No. 7,647,083, filed Mar. 1, 2006, titled Multiple Wavelength Sensor Equalization; U.S. Pat. No. 7,729,733, filed Mar. 1, 2006, titled Configurable Physiological Measurement System; U.S. Pat. Pub. No. 2006/0211925, filed Mar. 1, 2006, titled Physiological Parameter Confidence Measure and U.S. Pat. Pub. No. 2006/0238358, filed Mar. 1, 2006, titled Noninvasive Multi-Parameter Patient Monitor, all assigned to Masimo Laboratories, Irvine, Calif. (Masimo Labs) and all incorporated by reference herein. An advanced parameter measurement system that includes acoustic monitoring is described in U.S. Pat. Pub. No. 2010/0274099, filed Dec. 21, 2009, titled Acoustic Sensor Assembly, assigned to Masimo and incorporated by reference herein.

Advanced blood parameter measurement systems include Masimo Rainbow® SET, which provides measurements in addition to SpO₂, such as total hemoglobin (SpHbTM) oxygen content (SpOCTM), methemoglobin (SpMet®), carboxyhemoglobin (SpCO®) and PVI®. Advanced blood parameter sensors include Masimo Rainbow® adhesive, ReSposableTM and reusable sensors. Advanced blood parameter monitors include Masimo Radical-7TM, Rad-87TM and Rad-57TM monitors, all available from Masimo. Advanced parameter measurement systems may also include acoustic monitoring such as acoustic respiration rate (RRaTM) using a Rainbow Acoustic SensorTM and Rad-87TM monitor, available from Masimo. Such advanced pulse oximeters, low noise sensors and advanced physiological parameter measurement systems have also gained rapid acceptance in a wide variety of medical applications, including surgical wards, intensive care and neonatal units, general wards, home care, physical training, and virtually all types of monitoring scenarios.

FIGS. 1-3 illustrate problems and issues associated with physiological parameter measurement systems having fixed threshold alarm schemas. FIG. 1 illustrates a lower-limit, fixed-threshold alarm schema with respect to an oxygen saturation (SpO₂) parameter. Two alarm thresholds, D_L (delay) and ND_L (no delay), are defined. If oxygen saturation falls below D_L for a time delay greater than TD, an alarm is triggered. If oxygen saturation falls below ND_L an alarm is immediately triggered. D_L 120 is typically set around or somewhat above 90% oxygen saturation and ND_L 130 is typically set at 5% to 10% below D_L. For example, say a person's oxygen saturation 110 drops below D_L 120 at t=t₁ 162 and stays below D_L for at least a time delay TD 163. This triggers a delayed alarm 140 at t=t₂ 164, where t₂=t₁+

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TD. The alarm 140 remains active until oxygen saturation 110 rises above D_L 120 at t=t₃ 166. As another example, say that oxygen saturation 110 then drops below ND_L 130, which triggers an immediate alarm 150 at t=t4 168. The alarm 150 remains active until oxygen saturation 110 rises 5 above D_L 120 at t=t₅ 169.

FIG. 2 illustrates an upper-limit, fixed-threshold alarm schema with respect to an oxygen saturation (SpO₂) parameter. This alarm scenario is particularly applicable to the avoidance of ROP (retinopathy of prematurity). Again, two alarm thresholds, \mathbf{D}_U (delay) and \mathbf{ND}_U (no delay), are defined. D_{II} 220 might be set at or around 85% oxygen saturation and ND_U 230 might be set at or around 90% oxygen saturation. For example, a neonate's oxygen saturation 210 rises above D_{IJ} 220 at $t=t_1$ 262 and stays above D_{IJ} for at least a time delay TD 263. This triggers a delayed alarm 240 at $t=t_2$ 264, where $t_2=t_1+TD$. The alarm 240 remains active until oxygen saturation 210 falls below D_{II} **220** at $t=t_3$ **166**. Oxygen saturation **210** then rises above ND_U 20 230, which triggers an immediate alarm 250 at $t=t_4$ 268. The alarm 250 remains active until oxygen saturation 210 falls below D_U **220** at $t=t_5$ **269**.

FIG. 3 illustrates a baseline drift problem with the fixed threshold alarm schema described above. A person's oxygen 25 saturation is plotted on an oxygen saturation (SpO₂) versus time graph 300. In particular, during a first time interval T₁ 362, a person has an oxygen saturation 310 with a relatively stable "baseline" 312 punctuated by a shallow, transient desaturation event 314. This scenario may occur after the 30 person has been on oxygen so that baseline oxygen saturation is near 100%. Accordingly, with a fixed threshold alarm 330 set at, say, 90%, the transient event 314 does not trigger a nuisance alarm. However, the effects of oxygen treatments wear off over time and oxygen saturation levels drift down- 35 ward **350**. In particular, during a second time interval T₂ **364**, a person has an oxygen saturation 320 with a relatively stable baseline 322. The later baseline 322 is established at a substantially lower oxygen saturation than the earlier baseline 312. In this scenario, a shallow, transient desatu- 40 ration event 324 now exceeds the alarm threshold 330 and results in a nuisance alarm. After many such nuisance alarms, a caregiver may lower the alarm threshold 330 to unsafe levels or turn off alarms altogether, significantly hampering the effectiveness of monitoring oxygen satura- 45

A fixed threshold alarm schema is described above with respect to an oxygen saturation parameter, such as derived from a pulse oximeter. However, problematic fixed threshold alarm behavior may be exhibited in a variety of parameter measurement systems that calculate physiological parameters related to circulatory, respiratory, neurological, gastrointestinal, urinary, immune, musculoskeletal, endocrine or reproductive systems, such as the circulatory and respiratory parameters cited above, as but a few examples. 55

An adaptive alarm system, as described in detail below, advantageously provides an adaptive threshold alarm to solve false alarm and missed true alarm problems associated with baseline drift among other issues. For example, for a lower limit embodiment, an adaptive alarm system adjusts 60 an alarm threshold downwards when a parameter baseline is established at lower values. Likewise, for an upper limit embodiment, the adaptive alarm system adjusts an alarm threshold upwards in accordance with baseline drift so as to avoid nuisance alarms. In an embodiment, the rate of 65 baseline movement is limited so as to avoid masking of transients. In an embodiment, the baseline is established

along upper or lower portions of a parameter envelop so as to provide a margin of safety in lower limit or upper limit systems, respectively.

One aspect of an adaptive alarm system is responsive to a physiological parameter so as to generate an alarm threshold that adapts to baseline drift in the parameter and reduce false alarms without a corresponding increase in missed true alarms. The adaptive alarm system has a parameter derived from a physiological measurement system using a sensor in communication with a living being. A baseline processor calculates a parameter baseline from an average value of the parameter. Parameter limits specify an allowable range of the parameter. An adaptive threshold processor calculates an adaptive threshold from the parameter baseline and the parameter limits. An alarm generator is responsive to the parameter and the adaptive threshold so as to trigger an alarm indicative of the parameter crossing the adaptive threshold. The adaptive threshold is responsive to the parameter baseline so as to increase in value as the parameter baseline drifts to a higher parameter value and to decrease in value as the parameter baseline drifts to a lower parameter value.

In various embodiments, the baseline processor has a sliding window that identifies a time slice of parameter values. A trend calculator determines a trend from an average of the parameter values in the time slice. A response limiter tracks only the relatively long-term transitions of the trend. A bias calculator deletes the highest parameter values in the time slice or the lowest parameter values in the time slice so as to adjust the baseline to either a lower value or a higher value, respectively. The adaptive threshold becomes less response to baseline drift as the baseline approaches a predefined parameter limit. A first adaptive threshold is responsive to lower parameter limits and a second adaptive threshold is responsive to upper parameter limits. The alarm generator is responsive to both positive and negative transients from the baseline according to the first adaptive threshold and the second adaptive threshold. The first adaptive threshold is increasingly responsive to negative transients and the second adaptive threshold is decreasingly responsive to positive transients as the baseline trends toward lower parameter values.

Another aspect of an adaptive alarm system measures a physiological parameter, establishes a baseline for the parameter, adjusts an alarm threshold according to drift of the baseline and triggers an alarm in response to the parameter measurement crossing the alarm threshold. In various embodiments, the baseline is established by biasing a segment of the parameter, calculating a biased trend from the biased segment and restricting the transient response of the biased trend. The alarm threshold is adjusted by setting a parameter limit and calculating a delta difference between the alarm threshold and the baseline as a linear function of the baseline according to the parameter limit. The delta difference is calculated by decreasing delta as the baseline drifts toward the parameter limit and increasing delta as the baseline drifts away from the parameter limit. A parameter limit is set by selecting a first parameter limit in relation to a delayed alarm and selecting a second parameter limit in relation to an un-delayed alarm. A segment of the parameter is biased by windowing the parameter measurements, removing a lower value portion of the windowed parameter measurements and averaging a remaining portion of the windowed parameter measurements. An upper delta difference between an upper alarm threshold and the baseline is calculated and a lower delta difference between a lower alarm threshold and the baseline is calculated.

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A further aspect of an adaptive alarm system has a baseline processor that inputs a parameter and outputs a baseline according to a trend of the parameter. An adaptive threshold processor establishes an alarm threshold at a delta difference from the baseline. An alarm generator triggers an alarm based upon a parameter transient from the baseline crossing the alarm threshold. In various embodiments, a trend calculator outputs a biased trend and the baseline is responsive to the biased trend so as to reduce the size of a transient that triggers the alarm. A response limiter reduces baseline movement due to parameter transients. The adaptive threshold processor establishes a lower alarm threshold below the baseline and an upper alarm threshold above the baseline so that the alarm generator is responsive to both positive and negative transients from the baseline. The baseline processor establishes a lower baseline biased above the parameter trend and an upper baseline biased below the parameter trend. The lower alarm threshold is increasingly responsive to negative transients and the upper alarm threshold is decreasingly responsive to positive transients as the baseline trends toward lower parameter values.

DESCRIPTION OF THE DRAWINGS

FIGS. 1-3 are exemplar graphs illustrating problems and issues associated with physiological parameter measurement 25 systems having fixed threshold alarm schemas;

FIGS. 4A-B are general block diagrams of an adaptive alarm system having lower parameter limits;

FIGS. **5**A-B are a graph of a physiological parameter versus delta space and a graph of delta versus baseline, ³⁰ respectively, illustrating the relationship between a baseline, a lower-limit adaptive threshold and a variable difference delta between the baseline and the adaptive threshold;

FIG. **6** is an exemplar graph of a physiological parameter versus time illustrating an adaptive alarm system having a ³⁵ lower-limit adaptive threshold;

FIG. **7** is a graph of oxygen saturation versus time illustrating a baseline for determining an adaptive threshold; FIG. **8** is a graph of oxygen saturation versus time comparing adaptive-threshold alarm performance with ⁴⁰ fixed-threshold alarm performance;

FIGS. 9A-B are general block diagrams of an adaptive alarm system having upper parameter limits;

FIGS. **10**A-B are a graph of a physiological parameter versus delta space and a graph of delta versus baseline, ⁴⁵ respectively, illustrating the relationship between a baseline, an upper-limit adaptive threshold and a variable delta difference between the baseline and the adaptive threshold;

FIG. 11 is an exemplar graph of a physiological parameter versus time illustrating an adaptive alarm system having an 50 upper-limit adaptive threshold;

FIGS. 12A-B are general block diagrams of an adaptive alarm system having both lower alarm limits and upper alarm limits;

FIGS. 13A-E are physiological parameter versus delta 55 space graphs illustrating a lower-limit adaptive threshold, an upper-limit adaptive threshold, and a combined lower- and upper-limit adaptive threshold in various delta spaces; and

FIG. 14 is an exemplar graph of a physiological parameter versus time illustrating an adaptive alarm system having 60 both lower and upper alarm limits.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

FIGS. 4A-B illustrate an adaptive alarm system 400 embodiment having lower parameter limits L_1 and L_2 . As

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shown in FIG. 4A, the adaptive alarm system 400 has parameter 401, first limit (L_1) 403, second limit (L_2) 405 and maximum parameter value (Max) 406 inputs and generates a corresponding alarm 412 output. The parameter 401 input is generated by a physiological parameter processor, such as a pulse oximeter or an advanced blood parameter processor described above, as examples. The adaptive alarm system 400 has an alarm generator 410, a baseline processor 420, and an adaptive threshold processor 440. The alarm generator 410 has parameter 401 and adaptive threshold (AT) 442 inputs and generates the alarm 412 output accordingly. A baseline processor 420 has the parameter 401 input and generates a parameter baseline (B) 422 output. The baseline processor 420, is described in detail with respect to FIG. 4B, below. An adaptive threshold processor 440 has parameter baseline (B) 422, L_1 403, L_2 405 and Max 406 inputs and generates the adaptive threshold (AT) 442. The adaptive threshold processor 440 is described in detail with respect to FIGS. **5**A-B, below.

As shown in FIG. 4A, in an embodiment L_1 403 and L_2 405 may correspond to conventional fixed alarm thresholds with and without an alarm time delay, respectively. For an adaptive threshold schema, however, L_1 403 and L_2 405 do not determine an alarm threshold per se, but are reference levels for determining an adaptive threshold (AT) 442. In an embodiment, L_1 403 is an upper limit of the adaptive alarm threshold AT when the baseline is near the maximum parameter value (Max), and L_2 405 is a lower limit of the adaptive alarm threshold, as described in detail with respect to FIGS. 5A-B, below. In an exemplar embodiment when the parameter is oxygen saturation, L_1 403 is set at or around 90% and L_2 405 is set at 5 to 10% below L_1 , i.e. at 85% to 80% oxygen saturation. Many other L_1 and L_2 values may be used for an adaptive threshold schema as described herein.

Also shown in FIG. 4A, in an embodiment the alarm 412 output is triggered when the parameter 401 input falls below AT 442 and ends when the parameter 401 input rises above AT 442 or is otherwise cancelled. In an embodiment, the alarm 412 output is triggered after a time delay (TD), which may be fixed or variable. In an embodiment, the time delay (TD) is a function of the adaptive threshold (AT) 442. In an embodiment, the time delay (TD) is zero when the adaptive threshold (AT) is at the second lower limit (L₂) 405.

As shown in FIG. 4B, a baseline processor 420 embodiment has a sliding window 450, a bias calculator 460, a trend calculator 470 and a response limiter 480. The sliding window 450 inputs the parameter 401 and outputs a time segment 452 of the parameter 401. In an embodiment, each window incorporates a five minute span of parameter values. The bias calculator 460 advantageously provides an upward shift in the baseline (B) 422 for an additional margin of error over missed true alarms. That is, a baseline 422 is generated that tracks a higher-than-average range of parameter values, effectively raising the adaptive threshold AT slightly above a threshold calculated based upon a true parameter average, as shown and described in detail with respect to FIGS. 7-8, below. In an embodiment, the bias calculator 460 rejects a lower range of parameter values from each time segment **452** from the sliding window so as to generate a biased time segment 462.

Also shown in FIG. 4B, the trend calculator 470 outputs a biased trend 472 of the remaining higher range of parameter values in each biased segment 462. In an embodiment, the biased trend 462 is an average of the values in the biased time segment 462. In other embodiments, the biased trend 462 is a median or mode of the values in the biased time segment 462. The response limiter 480 advantageously

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limits the extent to which the baseline 422 output tracks the biased trend 472. Accordingly, the baseline 422 tracks only relatively longer-lived transitions of the parameter, but does not track (and hence mask) physiologically significant parameter events, such as oxygen desaturations for a ${\rm SpO}_2$ 5 parameter to name but one example. In an embodiment, the response limiter 480 has a low pass transfer function. In an embodiment, the response limiter 480 is a slew rate limiter.

FIGS. 5A-B further illustrate an adaptive threshold processor 440 (FIG. 4A) having a baseline (B) 422 input and 10 generating an adaptive threshold (AT) 442 output and a delta (Δ) 444 ancillary output according to parameter limits L₁ 403, L₂ 405 and Max 406, as described above. As shown in FIG. 5A, as the baseline (B) 422 decreases (increases) the adaptive threshold (AT) 444 monotonically decreases (increases) between L₁ 403 and L₂ 405. Further, as the baseline (B) 422 decreases (increases) the delta (Δ) 444 difference between the baseline (B) 422 and the adaptive threshold (AT) 442 monotonically decreases (increases) between Max-L₁ and zero.

As shown in FIG. 5B, the relationship between the delta (Δ) 444 and the baseline (B) 444 may be linear 550 (solid line), non-linear 560 (small-dash lines) or piecewise-linear (large-dash lines), to name a few. In an embodiment, the adaptive threshold processor 440 (FIG. 4A) calculates an 25 adaptive threshold (AT) 442 output in response to the baseline (B) 422 input according to a linear relationship. In a linear embodiment, the adaptive threshold processor 440 (FIG. 4A) calculates the adaptive threshold (AT) 442 according to EQS. 1-2:

$$\Delta = -\Big(\frac{Max-L_1}{Max-L_2}\Big)(Max-B) + (Max-L_1) \eqno(1)$$

$$AT=B-\Delta$$
 (2)

where Δ =Max-L₁ @ B=Max; Δ =0 @ B=L₂ and where AT=L₁ @ B=Max; AT=L₂ @ B=L₂, accordingly.

FIG. 6 illustrates the operational characteristics an adaptive alarm system 400 (FIG. 4A) having parameter limits Max 612, L_1 614 and L_2 616 and an alarm responsive to a baseline (B) 622, 632, 642; an adaptive threshold (AT) 628, 638, 648; and a corresponding Δ 626, 636, 646 according to EQS. 1-2, above. In particular, a physiological parameter 610 is graphed versus time 690 for various time segments t_1 , t_2 , t_3 692-696. The parameter range (PR) 650 is:

$$PR=Max-L_2$$
 (3)

and the adaptive threshold range (ATR) 660 is:

$$ATR=L_1-L_2 \tag{4}$$

As shown in FIG. 6, during a first time period t_1 **692**, a parameter segment **620** has a baseline (B) **622** at about Max **612**. As such, Δ **626**=Max-L₁ and the adaptive threshold 55 (AT) **628** is at about L₁ **614**. Accordingly, a transient **624** having a size less than Δ **626** does not trigger the alarm **412** (FIG. **4**A).

Also shown in FIG. 6, during a second time period t_2 **694**, a parameter segment **630** has a baseline (B) **632** at about L_1 **6014**. As such, Δ **636** is less than Max- L_1 and the adaptive threshold (AT) **638** is between L_1 and L_2 . Accordingly, a smaller transient **634** will trigger the alarm as compared to a transient **624** in the first time segment.

Further shown in FIG. 6, during a third time period t_3 696, 65 a parameter segment 640 has a baseline (B) 642 at about L_2 616. As such, Δ 646 is about zero and the adaptive threshold

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(AT) **648** is at about L_2 . Accordingly, even a small negative transient will trigger the alarm. As such, the behavior of the alarm threshold AT **628**, **638**, **648** advantageously adapts to higher or lower baseline values so as to increase or decrease the size of negative transients that trigger or do not trigger the alarm **412** (FIG. **4**A).

FIG. 7 is a parameter versus time graph 700 illustrating the characteristics of an adaptive alarm system 400 (FIGS. 4A-B), as described with respect to FIGS. 4-6, above, where the parameter is oxygen saturation (SpO₂). The graph 700 has a SpO₂ trace 710 and a superimposed baseline trace 720. The graph 700 also delineates tracking periods 730, where the baseline 720 follows the upper portions of SpO₂ values, and lagging periods 740, where the baseline 720 does not follow transient SpO2 events. The tracking time periods 730 illustrate that the baseline 720 advantageously tracks at the higher range of SpO₂ values 710 during relatively stable (flat) periods, as described above. Lagging time periods 740 illustrate that the baseline 720 is advantageously limited in 20 response to transient desaturation events so that significant desaturations fall below an adaptive threshold (not shown) and trigger an alarm accordingly.

FIG. 8 is a parameter versus time graph 800 illustrating characteristics of an adaptive alarm system 400 (FIGS. 4A-B), as described with respect to FIGS. 4-6, above, where the parameter is oxygen saturation (SpO₂). Vertical axis (SpO₂) resolution is 1%. The time interval 801 between vertical hash marks is five minutes. The graph 800 has a SpO₂ trace 810 and a baseline trace 820. The graph 800 also has a fixed threshold trace 830, a first adaptive threshold (AT) trace 840 and a second AT trace 850. The graph 800 further has a fixed threshold alarm trace 860, a first adaptive threshold alarm trace 870 and a second adaptive threshold alarm trace 880. In this example, L_1 is 90% and L_2 is 85% for the first AT trace 840 and first AT alarm trace 870. L₂ is 80% for a second AT trace 850 and a second AT alarm trace 880. The fixed threshold 830 results in many nuisance alarms 860. By comparison, the adaptive threshold alarm with $L_2=85\%$ has just one time interval of alarms 872 during a roughly 6% desaturation period (from 92% to 86%). The adaptive threshold alarm with L₂=80%, has no alarms during the 1 hour 25 minute monitoring period.

FIGS. 9A-B illustrate an adaptive alarm system 900 embodiment having upper parameter limits U₁ and U₂. As shown in FIG. 9A, the adaptive alarm system 900 has parameter 901, first limit (U1) 903, second limit (U2) 905 and minimum parameter value (Min) 906 inputs and generates a corresponding alarm 912 output. The parameter 901 input is generated by a physiological parameter processor, 50 such as a pulse oximeter or an advanced blood parameter processor described above, as examples. The adaptive alarm system 900 has an alarm generator 910, a baseline processor 920, and an adaptive threshold processor 940. The alarm generator 910 has parameter 901 and adaptive threshold (AT) 942 inputs and generates the alarm 912 output accordingly. A baseline processor 920 has the parameter 901 input and generates a parameter baseline (B) 922 output. The baseline processor 920, is described in detail with respect to FIG. 9B, below. An adaptive threshold processor 940 has parameter baseline (B) 922, U_1 903, U_2 905 and Min 906 inputs and generates the adaptive threshold (AT) 942. The adaptive threshold processor 940 is described in detail with respect to FIGS. 10A-B, below.

As shown in FIG. 9A, in an embodiment U₁ 903 and U₂ 905 may correspond to conventional fixed alarm thresholds with and without an alarm time delay, respectively. For an adaptive threshold schema, however, U₁ 903 and U₂ 905 do

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not determine an alarm threshold per se, but are reference levels for determining an adaptive threshold (AT) **942**. In an embodiment, U_1 **903** is a lower limit of the adaptive alarm threshold AT when the baseline is near the minimum parameter value (Min), and U_2 **905** is an upper limit of the adaptive 5 alarm threshold, as described in detail with respect to FIGS. **10**A-B, below. In an exemplar embodiment when the parameter is oxygen saturation, U_1 **903** is set at or around 85% and U_2 **905** is set at or around 90% oxygen saturation. Many other U_1 and U_2 values may be used for an adaptive threshold schema as described herein.

Also shown in FIG. **9A**, in an embodiment the alarm **912** output is triggered when the parameter **901** input rises above AT **942** and ends when the parameter **901** input falls below AT **942** or is otherwise cancelled. In an embodiment, the 15 alarm **912** output is triggered after a time delay (TD), which may be fixed or variable. In an embodiment, the time delay (TD) is a function of the adaptive threshold (AT) **942**. In an embodiment, the time delay (TD) is zero when the adaptive threshold (AT) is at the second upper limit (U₂) **905**.

As shown in FIG. 9B, a baseline processor 920 embodiment has a sliding window 950, a bias calculator 960, a trend calculator 970 and a response limiter 980. The sliding window 950 inputs the parameter 901 and outputs a time segment 952 of the parameter 901. In an embodiment, each 25 window incorporates a five minute span of parameter values. The bias calculator 960 advantageously provides a downward shift in the baseline (B) 922 for an additional margin of error over missed true alarms. That is, a baseline 922 is generated that tracks a lower-than-average range of param- 30 eter values, effectively lowering the adaptive threshold AT slightly below a threshold calculated based upon a true parameter average. In an embodiment, the bias calculator 960 rejects an upper range of parameter values from each time segment 952 from the sliding window so as to generate 35 a biased time segment **962**.

Also shown in FIG. 9B, the trend calculator 970 outputs a biased trend 972 of the remaining lower range of parameter values in each biased segment 962. In an embodiment, the biased trend 962 is an average of the values in the biased 40 time segment 962. In other embodiments, the biased trend 962 is a median or mode of the values in the biased time segment 962. The response limiter 980 advantageously limits the extent to which the baseline 922 output tracks the biased trend 972. Accordingly, the baseline 922 tracks only 45 relatively longer-lived transitions of the parameter, but does not track (and hence mask) physiologically significant parameter events, such as oxygen desaturations for a SpO₂ parameter to name but one example. In an embodiment, the response limiter 980 has a low pass transfer function. In an 50 embodiment, the response limiter 980 is a slew rate limiter.

FIGS. 10A-B further illustrate an adaptive threshold processor 940 (FIG. 9A) having a baseline (B) 922 input and generating an adaptive threshold (AT) 942 output and a delta (Δ) 944 ancillary output according to parameter limits U₁ 55 903, U₂ 905 and Min 906, as described above. As shown in FIG. 10A, as the baseline (B) 922 decreases (increases) the adaptive threshold (AT) 944 monotonically decreases (increases) between U₁ 903 and U₂ 905. Further, as the baseline (B) 922 decreases (increases) the delta (Δ) 944 difference 60 between the baseline (B) 922 and the adaptive threshold (AT) 942 monotonically decreases (increases) between Min–U₁ and zero.

As shown in FIG. 10B, the relationship between the delta (Δ) 944 and the baseline (B) 944 may be linear 550 (solid line), non-linear 560 (small-dash lines) or piecewise-linear (large-dash lines), to name a few. In an embodiment, the

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adaptive threshold processor **940** (FIG. **9**A) calculates an adaptive threshold (AT) **942** output in response to the baseline (B) **922** input according to a linear relationship. In a linear embodiment, the adaptive threshold processor **940** (FIG. **9**A) calculates the adaptive threshold (AT) **942** according to EQS. 5-6:

$$\Delta = -\left(\frac{U_{1} - Min}{U_{2} - Min}\right) (B - Min) + (U_{1} - Min)$$
 (5)

$$AT=B+\Delta$$
 (6)

where $\Delta = U_1$ -Min @ B=Min; $\Delta = 0$ @ B= U_2

and where $\widehat{AT}=U_1$ @ B=Min; $\widehat{AT}=U_2$ @ B= \widehat{U}_2 , accordingly. FIG. 11 illustrates the operational characteristics an adaptive alarm system 900 (FIG. 9A) having parameter limits Min 1112, U_1 1114 and U_2 1116 and an alarm responsive to a baseline (B) 1122, 1132, 1142; an adaptive threshold (AT) 1128, 1138, 1148; and a corresponding Δ 1126, 1136, 1146 according to EQS. 5-6, above. In particular, a physiological parameter 1110 is graphed versus time 1190 for various time segments t_1 , t_2 , t_3 1192-1196. The parameter range (PR) 1150 is:

$$PR=U_2-Min$$
 (7)

and the adaptive threshold range (ATR) 1160 is:

$$ATR=U_2-U_1 \tag{8}$$

As shown in FIG. 11, during a first time period t_1 1192, a parameter segment 1120 has a baseline (B) 1122 at about Min 1112. As such, Δ 1126=U₁-Min and the adaptive threshold (AT) 1128 is at about U₁ 1114. Accordingly, a transient 1124 having a size less than Δ 1126 does not trigger the alarm 912 (FIG. 9A).

Also shown in FIG. 11, during a second time period t_2 1194, a parameter segment 1130 has a baseline (B) 1132 at about U_1 1114. As such, Δ 1136 is less than U_1 -Min and the adaptive threshold (AT) 1138 is between U_1 and U_2 . Accordingly, a smaller transient 1134 will trigger the alarm as compared to a transient 1124 in the first time segment.

Further shown in FIG. 11, during a third time period t_3 1196, a parameter segment 1140 has a baseline (B) 1142 at about U_2 1116. As such, Δ 1146 is about zero and the adaptive threshold (AT) 1148 is at about U_2 . Accordingly, even a small positive transient will trigger the alarm. As such, the behavior of the alarm threshold AT 1128, 1138, 1148 advantageously adapts to higher or lower baseline values so as to increase or decrease the size of positive transients that trigger or do not trigger the alarm 912 (FIG. 9A).

FIGS. 12A-B illustrate an adaptive alarm system 1200 embodiment having lower limits L_1 , L_2 1203, such as described with respect to FIGS. 4A-B above, or upper limits U₁, U₂ 1205 such as described with respect to FIGS. 9A-B above, or both. As shown in FIG. 12A, the adaptive alarm system 1200 has parameter 1201, lower limit 1203 and upper limit 1205 inputs and generates a corresponding alarm **1212** output. The parameter **1201** input is generated by a physiological parameter processor, such as a pulse oximeter or an advanced blood parameter processor described above, as examples. The adaptive alarm system 1200 has an alarm generator 1210, a baseline processor 1220 and an adaptive threshold processor 1240. The alarm generator 1210 has parameter 1201 and adaptive threshold (AT) 1242 inputs and generates the alarm 1212 output accordingly. A baseline processor 1220 has the parameter 1201 input and generates

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one or more parameter baseline 1222 outputs. The baseline processor 1220, is described in detail with respect to FIG. 12B, below. An adaptive threshold processor 1240 has parameter baseline 1222, lower limit L_1 , L_2 1203 and upper limit U_1 , U_2 1205 inputs and generates lower and upper adaptive threshold AT_1 , AT_{μ} 1242 outputs. The adaptive threshold processor 1240 also generates ancillary upper and lower delta 1244 outputs. The adaptive threshold processor 1240 is described in detail with respect to FIGS. 13A-E, below.

As shown in FIG. 12A, in an embodiment L_1 , L_2 1203 and U_1 , U_2 1205 may correspond to conventional fixed alarm thresholds with an alarm delay (L_1 , U_1) and without an alarm delay (L_2 , U_2). For an adaptive threshold schema, however, these limits 1203, 1205 do not determine an alarm 15 threshold per se, but are reference levels for determining lower and upper adaptive thresholds AT_1 , AT_{11} 1242.

Also shown in FIG. 12A, in an embodiment the alarm 1212 output is triggered when the parameter 1201 input falls below AT_I 1242 and ends when the parameter 1201 input 20 rises above AT_I 1242 or the alarm is otherwise cancelled. Further, the alarm 1212 output is triggered when the parameter 1201 input rises above AT_u 1242 and ends when the parameter 1201 input falls below AT_u 1242 or the alarm is otherwise cancelled. In an embodiment, the alarm 1212 25 output is triggered after a time delay (TD), which may be fixed or variable. In an embodiment, the time delay (TD) is a function of the adaptive thresholds (AT_I, AT_u) 1242. In an embodiment, the time delay (TD) is zero when the lower adaptive threshold (AT_I) 1242 is at the second lower limit 30 (L_2) 1203 or when the upper adaptive alarm threshold AT_u 1242 is at the second upper limit (U_2) 1205.

As shown in FIG. 12B, a baseline processor 1220 embodiment has a sliding window 1250, an over-bias calculator 1260, an under-bias calculator 1265, trend calculators 1270 35 and response limiters 1280. The sliding window 1250 inputs the parameter 1201 and outputs a time segment 1252 of the parameter 1201. In an embodiment, each window incorporates a five minute span of parameter 1201 values.

Also shown in FIG. 12B, the over-bias calculator 1260 advantageously provides an upward shift in the lower baseline (B_I) 1282 for an additional margin of error over missed lower true alarms. That is, a lower baseline (B_I) 1282 is generated that tracks a higher-than-average range of parameter values, effectively raising the lower adaptive threshold 45 AT_I slightly above a threshold calculated based upon a true parameter average. In an embodiment, the over-bias calculator 1260 rejects a lower range of parameter values from each time segment 1252 of the sliding window 1250 so as to generate an over-biased time segment 1262.

Further shown in FIG. 12B, the under-bias calculator 1265 advantageously provides a downward shift in the upper baseline (B_u) 1287 for an additional margin of error over missed upper true alarms. That is, an upper baseline (B_u) 1287 is generated that tracks a lower-than-average range of 55 parameter values, effectively lowering the upper adaptive threshold AT_u slightly below a threshold calculated based upon a true parameter average. In an embodiment, the under-bias calculator 1267 rejects an upper range of parameter values from each time segment 1252 of the sliding 60 window 1250 so as to generate an under-biased time segment 1267.

Additionally shown in FIG. 12B, the trend calculator 1270 outputs an over-biased trend 1272 of the remaining higher range of parameter values in each over-biased segment 1262. Further, the trend calculator 1270 outputs an under-biased trend 1277 of the remaining lower range of

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parameter values in each under-biased segment 1267. In an embodiment, the biased trends 1272, 1277 are each an average of the values in the corresponding biased time segments 1262, 1267. In other embodiments, the biased trends 1272, 1277 are each a median or mode of the values in the corresponding biased time segments 1262, 1267. The response limiter 1280 advantageously limits the extent to which the baseline 1222 outputs track the biased trends 1272, 1277. Accordingly, the baseline 1222 outputs track only relatively longer-lived transitions of the parameter 1201, but do not track (and hence mask) physiologically significant parameter events. In an embodiment, the response limiter 1280 has a low pass transfer function. In an embodiment, the response limiter 1280 is a slew rate limiter.

FIGS. 13A-E illustrate parameter (P) operating ranges and ideal ranges in view of both lower and upper parameter limits. As shown in FIG. 13A, as the baseline (B_i) 1317 decreases (increases) the adaptive threshold (AT_i) 1318 monotonically decreases (increases) between L_1 and L_2 . Further, as the baseline (B_i) 1317 decreases (increases) the delta (Δ_i) 1319 difference between the baseline (B_i) 1317 and the adaptive threshold (AT_i) 1318 monotonically decreases (increases) between Max- L_1 and 0.

As shown in FIG. 13B, as the baseline (B_u) 1327 increases (decreases) the adaptive threshold (AT_u) 1328 monotonically increases (decreases) between U_1 and U_2 . Further, as the baseline (B_u) 1327 increases (decreases) the delta (Δ_u) 1329 difference between the adaptive threshold (AT_u) 1328 and the baseline (B_u) 1327 monotonically decreases (increases) between Min– U_1 and 0.

As shown in FIG. 13C, combining FIGS. 13A-B, the parameter (P) operating range is bounded by the overlapping regions of 13A and 13B 1330 having an upper bound of U_2 and a lower bound of L_2 . In particular, L_1 , L_2 are the upper and lower limits of the lower adaptive alarm threshold AT_i ; and U_2 , U_1 are the upper and lower limits of the upper adaptive alarm threshold AT_u .

FIG. 13D illustrates parameter (P) versus the overlapping independent delta domains F_u , F_I for upper and lower baselines B_u , B_I ; adaptive thresholds AT_u , AT_I and deltas Δ_u , Δ_I , based upon FIGS. 13A-C. FIG. 13E illustrates parameter (P) versus the overlapping independent delta domains F_u , F_I (reversed); for upper and lower baselines B_u , B_I ; adaptive thresholds AT_u , AT_I and deltas Δ_u , Δ_I ,

As shown in FIG. 13E, the equations for bi-lateral adaptive thresholds are:

$$\Delta_u = -\left(\frac{U_1 - L_2}{U_2 - L_2}\right) (B - L_2) + (U_1 - L_2)$$
⁽⁹⁾

$$AT_{u}=B+\Delta_{u} \tag{10}$$

55 where $\Delta_{u} = U_{1} - L_{2}$ @ $B = L_{2}$; and $\Delta_{u} = 0$ @ $B = U_{2}$; and where $AT_{u} = U_{1}$ @ $B = L_{2}$; and $AT_{u} = U_{2}$ @ $B = U_{2}$. Further:

$$\Delta_{l} = \left(\frac{U_{2} - L_{1}}{U_{2} - L_{2}}\right) (B - L_{2}) \tag{11}$$

$$AT_{I} = B - \Delta_{I} \tag{12}$$

where $\Delta_{l}=U_{2}-L_{1}$ @ B=U₂; and $\Delta_{l}=0$ @ B=L₂; and where AT_{$l}=L_{1}$ @ B=U₂; AT_{$l}=L_{2}$ @ B=L₂.</sub></sub>

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Although shown as a linear relationship, in general:

$$\Delta_l = f_1(B); \Delta_u = f_2(B)$$

That is, Δ_I and Δ_u can each be a linear function of B, a non-linear function of B or a piecewise linear function of B, 5 to name a few, in a manner similar to that described with respect to FIGS. **5**B and **10**B, above.

FIGS. 14A-B illustrate the operational characteristics an adaptive alarm system 1200 (FIGS. 12A-B) having upper limits U_1 , U_2 1412, 1414 and lower limits L_1 , L_2 1422, 1424. ¹⁰ An alarm 1212 (FIG. 12A) output is responsive to a baseline (B) 1432, 1442, 1452, 1462; an upper delta (Δ_u) 1437, 1447, 1457, 1467; and a corresponding upper adaptive threshold (AT_u) 1439, 1449, 1459, 1469, according to EQS. 9-10, above. Further, the alarm 1212 (FIG. 12A) output is responsive to a lower delta (Δ_l) 1436, 1446, 1456, 1466 and a corresponding lower adaptive threshold (AT_l) 1438, 1448, 1458, 1468, according to EQS. 11-12, above.

As shown in FIGS. **14**A-B, a physiological parameter **1410** is graphed versus time **1490** for various time segments t_1 , t_2 , t_3 , t_4 **1492-1498**. The parameter range (PR) **1480** is:

$$PR=U_2-L_2$$
 (13)

the lower adaptive threshold AT_t range is:

$$ATR_{\bar{l}} = L_1 - L_2 \tag{14}$$

the upper adaptive threshold AT_U range is:

$$ATR_{r}=U_{2}-U_{1} \tag{15}$$

As shown in FIG. 14A, during a first time period t_1 1492, a parameter segment 1430 has a baseline (B) 1432 at about U_2 1414. As such, Δ_I 1436= U_2 - L_1 ; Δ_u 1437=0; AT_I 1438= L_1 ; AT_u 1439= U_2 . Accordingly, a negative transient 1434 having a size less than U_2 - L_1 does not trigger an alarm.

Also shown in FIG. 14A, during a second time period t_2 1494, a parameter segment 1440 has a baseline (B) 1442 less than U_2 . As such, Δ_1 1446 is less than U_1 – L_1 and the adaptive threshold (AT_u) 1447 is between U_1 and U_2 . Accordingly, a smaller negative transient 1444 will trigger the alarm as compared to the negative transient 1434 in the first time segment 1430.

Further shown in FIG. 14A, during a third time period t_3 1496, a parameter segment 1450 has a baseline (B) 1452 less than U_1 1412. As such, a smaller negative transient 1454 will trigger the alarm as compared to the negative transient 1444 in the second time segment 1440. However, a larger positive transient 1455 is needed to trigger the alarm as compared to the positive transient 1445 in the second time segment 1440.

Additionally shown in FIG. 14A, during a fourth time period t_4 1460, a parameter segment 1460 has a baseline (B) 1462 at about L_2 1424. As such, Δ_l 1466=0; Δ_u 1467= U_1 - L_2 ; AT $_l$ 1468= L_2 ; AT $_u$ 1469= U_1 . Accordingly, a positive transient 1465 having a size less than U_1 - L_2 does not trigger an alarm.

An adaptive alarm system has been disclosed in detail in connection with various embodiments. These embodiments are disclosed by way of examples only and are not to limit the scope of the claims that follow. One of ordinary skill in the art will appreciate many variations and modifications.

What is claimed is:

1. A system for reducing electronic alarms in a medical patient monitoring system, the system comprising:

an optical sensor configured to transmit optical radiation into a tissue site of a patient and detect attenuated 65 optical radiation indicative of at least one physiological parameter of a patient; and 14

one or more hardware processors in electronic communication with the optical sensor, the one or more hardware processors configured to:

[measure] determine oxygen saturation values of [a] the patient over a first period of time;

[determine if] when at least one oxygen saturation value obtained over the first period of time exceeds a first alarm threshold[;], determine whether a first alarm should be triggered [based on the determination that the at least one oxygen saturation value obtained over the first period of time exceeds the first alarm threshold];

[determine] access a second alarm threshold to be applied during a second period of time subsequent to the first period of time, the second alarm threshold replacing the first alarm threshold, wherein the second alarm threshold [being determined by:

comparing at least a first oxygen saturation value obtained during the first time period with a lower limit associated with oxygen saturation; and

computing a second alarm threshold based on the comparison where the second alarm threshold is computed to be at] has a value less than the at least [first] one oxygen saturation value and greater than [the] a lower limit and at an offset from the [first] at least one oxygen saturation value, wherein the offset [is configured to diminish] is diminished as a difference between the at least first oxygen saturation value and the lower limit diminishes:

[measure] determine oxygen saturation values of [a] the patient over the second period of time [to determine at least a second oxygen saturation value]; and

[determine whether] trigger a second alarm [should be triggered by determining if] based on at least one value of the oxygen saturation [value] values obtained [during] over the second period of time [exceeds] exceeding the second alarm threshold [and triggering an alarm if it is determined the second alarm should be triggered].

- 2. The system of claim 1, wherein the one or more hardware processors are configured to calculate a first baseline measurement from the [measured] oxygen saturation values over the first period of time and wherein the at least one [oxygen saturation] value obtained during the first period of time corresponds to the first baseline measurement.
- 3. The system of claim 2, wherein the one or more hardware processors are configured to calculate a second baseline measurement from the [measured] oxygen saturation values over the second period of time and wherein the at least one [oxygen saturation] value obtained during the second period of time corresponds to the second baseline measurement.
- **4**. The system of claim **1**, wherein the lower limit is [predefined] *predetermined* and corresponds to a minimum parameter value for oxygen saturation.
- 5. The system of claim 1, wherein the one or more hardware processors are further configured to wait for a time delay prior to the triggering of the second alarm, and wherein the time delay is a function of the second alarm threshold.
- 6. The system of claim 5, wherein the time delay decreases as the difference between the at least [first oxygen saturation] *one* value and the lower limit diminishes.
- 7. The system of claim 1, wherein the first alarm threshold is predetermined.

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- **8**. A system for reducing electronic alarms in a medical patient monitoring system including a pulse oximeter in communication with an optical sensor, the system comprising one or more hardware processors configured to:
 - [measure] determine oxygen saturation values of a patient over a first period of time;
 - determine if at least one oxygen saturation value obtained over the first period of time exceeds a first alarm threshold:
 - [determine whether a first alarm should be triggered based 10 on the determination that the at least one oxygen saturation value obtained over the first period of time exceeds the first alarm threshold;
 - compare at least a first oxygen saturation value obtained during the first time period with a lower limit associated with oxygen saturation;
 - compute] access a second alarm threshold [based on the comparison];
 - [determine] apply a time delay based on the [computed] second alarm threshold, wherein the time delay ²⁰ approaches zero as the [first] at least one oxygen saturation value obtained over the first period of time approaches the lower limit;
 - [measure] determine oxygen saturation values of [a] the patient over [the] a second period of time [to determine 25 at least a second oxygen saturation value] different from the first period; and
 - [determine whether] *trigger* a second alarm [should be triggered by determining if] *based on the* at least one oxygen saturation value obtained during the second ³⁰ period of time [exceeds] *exceeding* the second alarm threshold [for the time delay and triggering an alarm if it is determined the second alarm should be triggered].
 - where the second alarm threshold is at a value less than the at least one oxygen saturation value and greater 35 than the lower limit and at an offset from the at least one oxygen saturation value, wherein the offset is diminished as a difference between the at least one oxygen saturation value and the lower limit diminishes.
- 9. The system of claim 8, wherein the first alarm threshold 40 is predetermined.
- 10. The system of claim 8, wherein the lower limit is [predefined] *predetermined* and corresponds to a minimum parameter value for oxygen saturation.
- [11. The system of claim **8**, where the second alarm ⁴⁵ threshold is computed to be at a value less than the at least first oxygen saturation value and greater than the lower limit and at an offset from the first oxygen saturation value, wherein the offset is configured to diminish as a difference between the at least first oxygen saturation value and the ⁵⁰ lower limit diminishes.]
- **12**. An electronic method [for] *of* reducing electronic alarms in a medical patient monitoring system, the electronic method comprising:
 - measuring, with a pulse oximeter including a light source, 55 an optical detector and one or more hardware processors configured to receive signals responsive to light attenuated by tissue of a patient, oxygen saturation values of [a] the patient over a first period of time;
 - determining, using the one or more hardware processors, 60 if at least one oxygen saturation value [determined] measured over the first period of time exceeds a first alarm threshold;

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- [determining whether a first alarm should be triggered based on the determination that at least one oxygen saturation value obtained during the first period of time exceeds the first alarm threshold;
- comparing at least a first oxygen saturation value obtained during the first time period with a lower limit associated with oxygen saturation;
- computing the applying, using the one or more hardware processors, a second alarm threshold [based on the comparison where the second alarm threshold is computed to be] at a value (i) less than [the at least first] an oxygen saturation value [and] of the patient, (ii) greater than [the] a lower limit, (iii) and at an offset from the [first] oxygen saturation value of the patient, wherein the offset [is configured to diminish] is diminished as a difference between the [at least first] oxygen saturation value and the lower limit diminishes and wherein [the second alarm threshold is configured to be applied during a second period of time subsequent to the first period of time,] the second alarm threshold [replacing] replaces the first alarm threshold;
- measuring, using the pulse oximeter, oxygen saturation values of [a] the patient over the second period of time to determine at least a second oxygen saturation value; and
- determining, using the one or more hardware processors, whether to trigger a second alarm [should be triggered] by at least determining if at least one oxygen saturation value obtained during the second period of time exceeds the second alarm threshold [and triggering an alarm if it is determined the second alarm should be triggered].
- 13. The electronic method of claim 12, wherein [the one or more hardware processors are configured to calculate] the electronic method further comprises, using the one or more hardware processors, calculating a first baseline measurement from the measured oxygen saturation values over the first period of time and wherein the at least one oxygen saturation value obtained during the first period of time corresponds to the first baseline measurement.
- 14. The electronic method of claim 13, wherein [the one or more hardware processors are configured to calculate] the electronic method further comprises, using the one or more hardware processors, calculating a second baseline measurement from the measured oxygen saturation values over the second period of time and wherein the at least one oxygen saturation value obtained during the second period of time corresponds to the second baseline measurement.
- 15. The electronic method of claim 12, wherein the lower limit is [predefined] *predetermined* and corresponds to a minimum parameter value for oxygen saturation.
- 16. The electronic method of claim 12, wherein [the one or more hardware processors are further configured to wait] the electronic method further comprises, using the one or more hardware processors, waiting for a time delay prior to the triggering of the second alarm, and wherein the time delay is a function of the second alarm threshold.
- 17. The electronic method of claim 16, wherein the time delay decreases as the difference between the at least [first] *one* oxygen saturation value and the lower limit diminishes.
- 18. The electronic method of claim 12, wherein the first alarm threshold is predetermined.

* * * * *

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(54) ALARM SUSPEND SYSTEM

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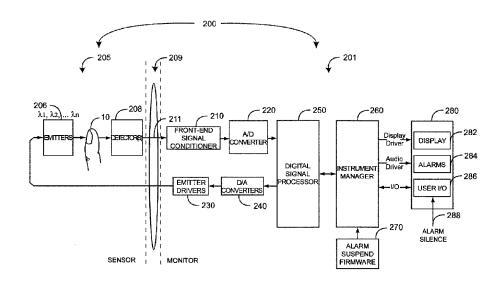
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(57) ABSTRACT

An alarm suspend system utilizes an alarm trigger responsive to physiological parameters and corresponding limits on those parameters. The parameters are associated with both fast and slow treatment times corresponding to length of time it takes for a person to respond to medical treatment for out-of-limit parameter measurements. Audible and visual alarms respond to the alarm trigger. An alarm silence button is pressed to silence the audible alarm for a predetermined suspend time. The audible alarm is activated after the suspend time has lapsed. Longer suspend times are associated with slow treatment parameters and shorter suspend times are associated with fast treatment parameters.

26 Claims, 5 Drawing Sheets



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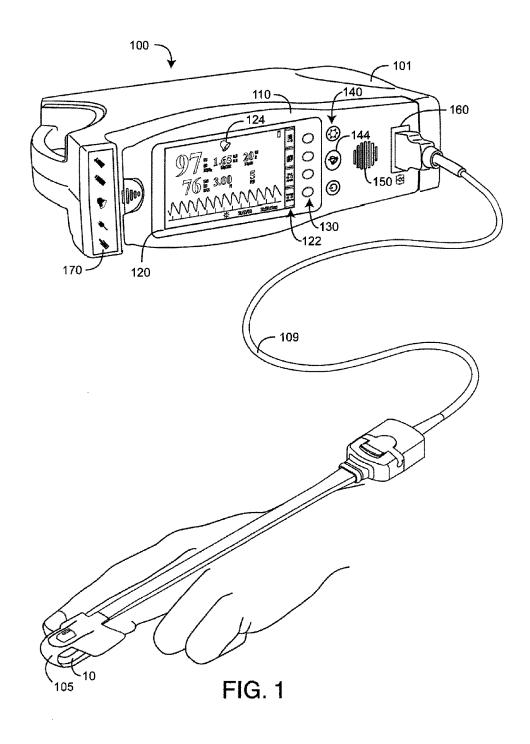
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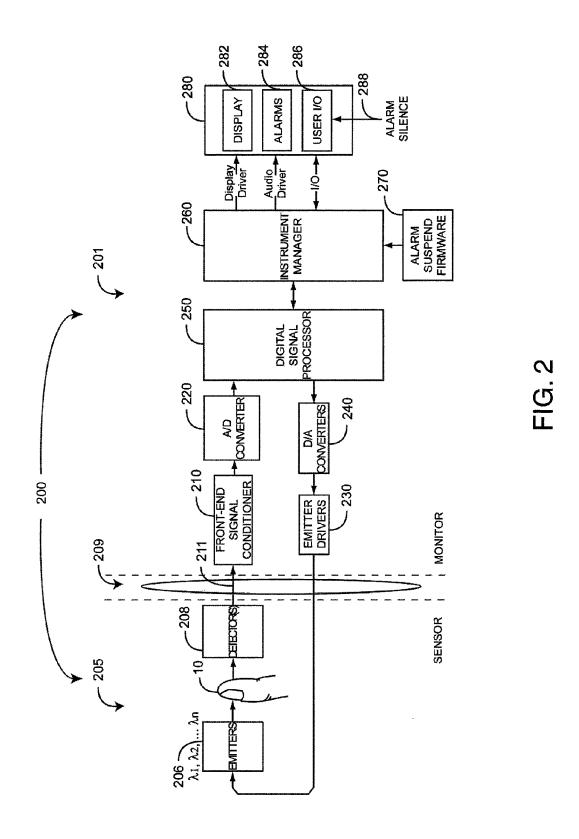
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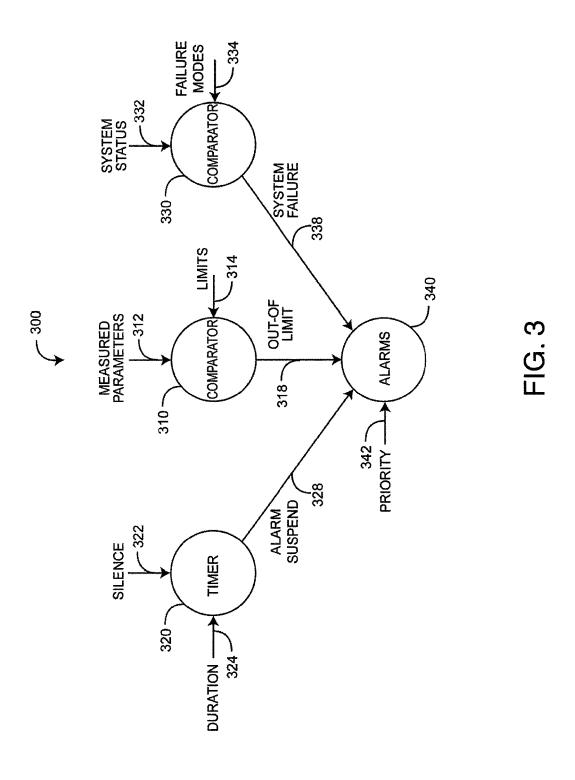
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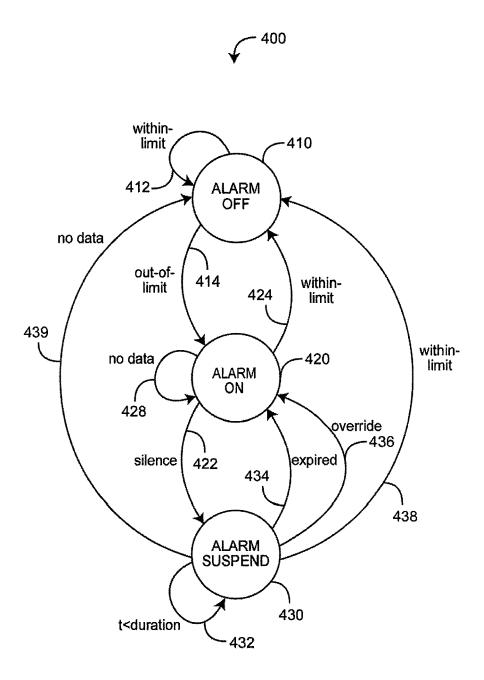


FIG. 4

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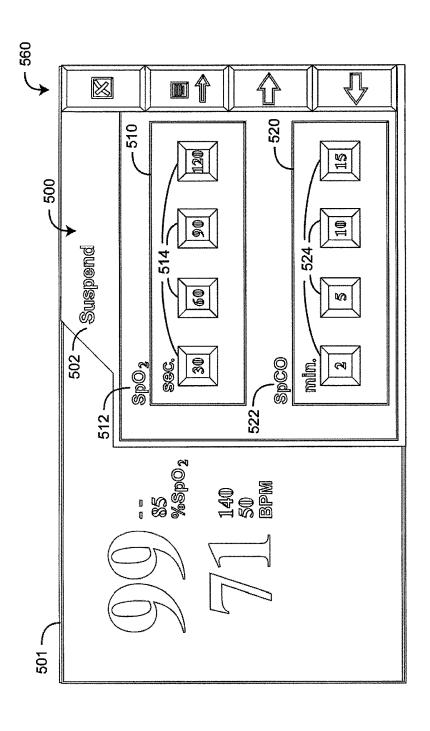


FIG. 5

1 ALARM SUSPEND SYSTEM

Matter enclosed in heavy brackets [] appears in the original patent but forms no part of this reissue specification; matter printed in italics indicates the additions made by reissue; a claim printed with strikethrough indicates that the claim was canceled, disclaimed, or held invalid by a prior post-patent action or proceeding.

CROSS-REFERENCE TO RELATED APPLICATIONS

This [application] is an application for reissue of U.S. Pat. No. 9,153,121, issued on Oct. 6, 2015 and titled "Alarm 15 Suspend System," which is a continuation of U.S. patent application Ser. No. 14/036,496, filed Sep. 25, 2013 and titled "Alarm Suspend System," which is a continuation of U.S. patent application Ser. No. 13/476,725, filed May 21, 2012 and titled "Alarm Suspend System," which is a con- 20 tinuation of U.S. patent application Ser. No. 12/510,982 filed Jul. 28, 2009 and titled "Alarm Suspend System," which claims priority benefit under 35 U.S.C. §119(e) to U.S. Provisional Patent Application Ser. No. 61/084,615, filed Jul. 29, 2008, titled "Alarm Management System[.];" more 25 than one reissue application has been filed for the reissue of U.S. Pat. No. 9,153,121, including U.S. patent application Ser. No. 15/583,935 (the present application), U.S. patent application Ser. No. 15/583,922, and U.S. patent application Ser. No. 15/583,948. All of the above-referenced applica- 30 tions are hereby incorporated by reference herein in their entireties.

BACKGROUND

Pulse oximetry for measuring constituents of circulating blood has achieved acceptance in a wide variety of medical applications, including surgical wards, intensive care and neonatal units, general wards, home care, physical training, and virtually all types of monitoring scenarios. A pulse 40 oximeter generally includes a two-wavelength optical sensor applied to a patient, a monitor for processing sensor signals and displaying results and a patient cable electrically interconnecting the sensor and the monitor. The monitor typically provides a numerical readout of physiological parameters 45 such as oxygen saturation (SpO₂) and pulse rate (PR). Advanced physiological monitors utilize multiple wavelength sensors and enhanced measurement capabilities to provide readouts of additional parameters, such as carboxyhemoglobin (HbCO), methemoglobin (HbMet) and total 50 hemoglobin (Hbt).

Pulse oximeters capable of reading through motion induced noise are disclosed in at least U.S. Pat. Nos. 6,770,028, 6,658,276, 6,650,917, 6,157,850, 6,002,952, 5,769,785 and 5,758,644; low noise pulse oximetry sensors 55 are disclosed in at least U.S. Pat. Nos. 6,088,607 and 5,782,757; all of which are assigned to Masimo Corporation, Irvine, Calif. ("Masimo") and are incorporated by reference herein.

Physiological monitors and corresponding multiple wavelength optical sensors are described in at least U.S. patent application Ser. No. 11/367,013, filed Mar. 1, 2006 and titled Multiple Wavelength Sensor Emitters and U.S. patent application Ser. No. 11/366,208, filed Mar. 1, 2006 and titled Noninvasive Multi-Parameter Patient Monitor, both 65 assigned to Masimo Laboratories, Irvine, Calif. (Masimo Labs) and both incorporated by reference herein.

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Further, physiological monitoring systems that include low noise optical sensors and pulse oximetry monitors, such as any of LNOP® adhesive or reusable sensors, SofTouchTM sensors, Hi-Fi TraumaTM or BlueTM sensors; and any of Radical®, SatShareTM, Rad-9TM, Rad-5TM, Rad-5TM, Rad-5vTM or PPO+TM Masimo SET® pulse oximeters, are all available from Masimo. Physiological monitoring systems including multiple wavelength sensors and corresponding noninvasive blood parameter monitors, such as RainbowTM adhesive and reusable sensors and RAD-57TM and Radical-7TM monitors for measuring SpO₂, pulse rate (PR), perfusion index (PI), pleth variability index (PVI), signal quality, HbCO and HbMet among other parameters are also available from Masimo.

SUMMARY OF THE INVENTION

Monitor alarms are triggered by out-of-limit parameters and system failures, the latter including monitor or sensor failures or improper sensor placement, to name a few. Alarms can be visual, audible or both. Alarms can also have different levels of priority, which are reflected in the type of visual and audible alarms. In an embodiment, parameters exceeding limits such as low SpO₂, high HbCO, high HbMet and low and high BPM trigger high priority alarms. System failures due to sensor off, no sensor or defective sensor also trigger high priority alarms. Parameters exceeding limits such as high SpO₂, low and high PI, low and high PVI, for example, trigger medium priority alarms. Parameters exceeding limits such as low HbCO and low HbMet along with a system low battery indication are examples of low priority alarms.

An audible alarm may be temporarily suspended by pressing an alarm silence button so as to prevent unnecessary disturbance to the patient and distraction of the caregiver. During alarm suspension, visual alarms remain active. If an alarm condition persists after a predetermined alarm suspend period, the audible alarm resumes. The alarm suspend period is typically long enough to give a caregiver sufficient time to intervene with appropriate patient treatment yet short enough to ensure that patient health is not endangered if intervention is ineffective. For conventional pulse oximetry, an alarm suspend may be, for example, a maximum of 120 seconds.

Alarm suspension on advanced blood parameter monitors is problematic. With conventional pulse oximetry, treatment for abnormal parameter measurements can be quickly applied and a patient response is typically fast. For example, a treatment for low oxygen saturation is the application of an oxygen mask or an increase in oxygen flow. By contrast, the duration of treatment for parameters measured by advanced monitors is highly dependent on the alarm-triggering parameter. For example, the treatment for high methemoglobin is the injection of methylene blue, and the patient response to such an injection is slow. When patient treatment time exceeds the maximum alarm suspend period, an audible alarm will constantly reactivate. Thus, a single alarm suspend duration for all parameters is inadequate to cope with the many different types of parameters measured by advanced monitors.

One aspect of an alarm suspend system for silencing the alarms is an alarm trigger responsive to any of various parameters and predetermined limits corresponding to the parameters, where the parameters are partitioned according to treatment time, i.e. the relative length of time it takes for a person to respond to medical treatment for a parameter measurement outside of the predetermined limits. An

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audible alarm is responsive to the alarm trigger. An alarm silence button is actuated so as to suspend the audible alarm. A timer tracks the duration of the suspended alarm and is initiated by actuation of an alarm silence button. The timer retriggers the audible alarm after the timed duration has 5 lapsed/expired. In an embodiment, a long duration suspend time is associated with slow treatment parameters and a short duration suspend time is associated with fast treatment parameters. Fast treatment parameters may include, for example, parameters relating to normal blood hemoglobin 10 constituents and slow treatment parameters may include parameters relating to abnormal blood hemoglobin constitu-

In various embodiments, a short duration suspend time is less than or equal to about two minutes and a long duration 15 measurement system utilizing an alarm suspend system; suspended time is greater than about two minutes. A default duration associated with the fast treatment parameters is about two minutes and a default duration associated with the slow treatment parameters is about fifteen minutes. The alarm suspend system may also have an alarm suspend 20 override responsive to a predetermined unit change in the parameter triggering a suspended alarm. The override results in reactivation of the suspended alarm. A physiological monitor having an alarm suspend system may also have a pop-up window that appears on the monitor display in 25 response to actuation of the silence button, where the pop-up window presents a choice of alarm suspend durations.

Another aspect of an alarm suspend system is a partition of measured parameters into at least a first group and a second group. An audible alarm is triggered if at least one 30 parameter is outside of predetermined limits. The audible alarm is suspended in response to a silence request. A first duration is associated with the first group and a second duration is associated with the second group. The audible alarm is reactivated after at least one of the first duration and 35 the second duration. The first duration may be set so as to generally correspond to a first range of treatment times for the first group of parameters. Likewise, the second duration may be set so as to generally correspond to a second range of treatment times for the second group of parameters, where 40 the first range of treatment times and the second range of treatment times are non-overlapping.

In various embodiments, suspended audible alarms are overridden if the triggering parameter has greater than a predetermined unit change before the suspended alarm 45 expires according to either the first duration or the second duration. The first and second groups are defined in relation to normal hemoglobin measurements abnormal hemoglobin measurements, respectively. The first duration is set to be less than or equal to two minutes and the second duration is 50 set to be greater than two minutes, with default durations of about two minutes corresponding to the first group and about fifteen minutes corresponding to the second group. In an embodiment, a pop-up window for a monitor display is constructed and the first duration and the second duration are 55 selected from a range of durations presented within the pop-up window.

A further aspect of an alarm suspend system deactivates an audible alarm for one of a short duration and a long duration according to the alarm-triggering parameter. A first 60 group of parameters is associated with the short duration and a second group of parameters is associated with the long duration. The first group and the second group are partitioned according to a fast treatment time and a short treatment time associated with the parameters. An override 65 reactivates the audible alarm if the trigger parameter changes more than a predetermine amount during the cor-

responding duration. In various embodiments, the first group comprises parameters related to the measurement of normal hemoglobin and the second group comprises parameters related to the measurement of abnormal hemoglobin. The long duration is greater than about 120 seconds and the short duration is less than or equal to about 120 seconds. A pop-up window for the display allows selection of the long duration and the short duration in response to the silence button.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of a physiological measurement system utilizing an alarm suspend system;

FIG. 2 is a detailed block diagram of a physiological

FIG. 3 is a flow diagram of an alarm suspend system embodiment;

FIG. 4 is a state diagram of an alarm suspend system embodiment; and

FIG. 5 is an illustration of an alarm suspend pop-up window.

DETAILED DESCRIPTION

FIG. 1 illustrates a physiological measurement system 100 that utilizes an alarm suspend system. The physiological measurement system 100 has a noninvasive sensor 105 attached to a tissue site ${\bf 10}$, a physiological monitor ${\bf 101}$, and an interface cable 109 interconnecting the monitor 101 and the sensor 105. The physiological measurement system 100 may incorporate pulse oximetry in addition to advanced features, such as a multiple wavelength sensor and advanced processes for determining physiological parameters other than or in addition to those of pulse oximetry, such as carboxyhemoglobin, methemoglobin and total hemoglobin, as a few examples.

The monitor 101 has a front panel 110 providing a display 120, touch keys 130, controls 140, a speaker 150, a sensor port 160 and status indicators 170. The display 120 shows parameter readouts, limits and waveforms among other items. The display 120 also has touch key icons 122 that indicate touch key 130 functions. The speaker 150 provides an audible alarm in response to physiological measurements that violate preset conditions, such as an out-of-limit parameter, as well as system failures, such as a low battery condition. The controls 140 include an alarm silence button 144 that is pressed to temporarily suspend out-of-limit parameter alarms and system alarms, such as low battery. The display 120 provides visual alarms, which include a bell-shaped alarm status indicator 124 that illuminates during an alarm condition and parameter readouts 210 and limits 220 that flash when parameters are out-of-limit. Status indicators 170 also provide visual alarms. When there are multiple alarm conditions, the parameter displays 202 indicate parameters with the highest alarm priority. Touch keys 130 and corresponding icons 122 include an alarm menu access button for setting alarm conditions, such as high or low alarm limits for SpO₂, HbCO, HbMet, PR and PI. The alarm silence button 144 is pressed to temporarily suspend audible alarms. Advantageously, an alarm suspend system provides a parameter-dependent variation in the alarm suspend duration, as described below, utilizing a common silence button or other suspend initiator.

FIG. 2 illustrates a physiological measurement system 200 including a physiological monitor 201, a sensor 205 and an interface cable 209. The sensor 205 is attached to a tissue site, such as a finger 10, and includes a plurality of emitters

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206 irradiating the tissue site 10 with multiple wavelengths of light. The sensor 205 also includes one or more detectors 208 capable of detecting the light after attenuation by the tissue site 10. The sensor 205 transmits optical radiation at wavelengths other than or including the red and infrared 5 wavelengths utilized in pulse oximeters. The monitor 201 inputs a corresponding sensor signal 211 and determines the relative concentrations of blood constituents other than or in addition to the "normal" blood hemoglobin constituents $\rm HbO_2$ and $\rm Hb$, including "abnormal" blood hemoglobin 10 constituents $\rm HbC_0$, $\rm HbMet$ and blood related parameters such as fractional oxygen saturation, total hemoglobin and blood glucose to name a few.

As shown in FIG. 2, the monitor 201 has a front-end signal conditioner 210, an A/D converter 220, emitter drivers 230, D/A converters 240 and a digital signal processor ("DSP") 250. In general, the emitter drivers 230 convert digital control signals, via the D/A converters 240, into analog drive signals capable of driving the sensor emitters 206. The front-end signal conditioner 210 converts, via the 20 A/D converter 220, composite analog intensity signal(s) from light sensitive detector(s) 208 into digital data input to the DSP 250. The emitter drivers 230 and front-end signal conditioner 210 communicate with the sensor 205 via the interface cable 209.

Also shown in FIG. 2, the monitor 201 has an instrument manager 260 and a user interface 280. The user interface 280 includes one or more displays 282, alarms 284 and user input/output (I/O) 286. The instrument manager 260 communicates with the DSP 250 to receive parameter data and 30 to present that data on the display 282. The instrument manager 260 may also store and display historical or trending data related to one or more of the measured parameters or combinations of the measured parameters. The instrument manager 260 also controls audible and visual alarms and 35 indicators 284. The instrument manager 260 responds to user-actuated keys and communicates with external devices via various I/O ports 286. Further, the instrument manager 260 executes alarm suspend firmware 270 so as to respond to an alarm silence button press 288, as described in detail 40 with respect to FIGS. 3-4.

FIG. 3 generally illustrates an alarm suspend system 300. Alarm triggers include system failures 338 and out-of-limit parameters 318. Triggered alarms 340 may be audible, visual or both, and may vary according to priority 342. 45 Audible alarms may be generated by a monitor front-panel-mounted speaker 150 (FIG. 1) and may vary in loudness, pitch and sound pattern. Visual alarms may include parameter labels, parameter numerics, symbols and status lights, which can flash and vary in color.

As shown in FIG. 3, measured parameters 312 are compared 310 to default or user-specified limits 314. An out-of-limit condition 318 triggers an alarm 340. An alarm suspend 328 is user-initiated by a silence request 322. This may be a press of a silence button 144 (FIG. 1) on a monitor 55 front panel 110 (FIG. 1). In an embodiment, the alarm suspend 328 silences audible alarms and modifies the display of visual alarms. The alarm suspend 328 is based on a timer 320, which ends the alarm suspend 328 after a predetermined duration 324. The duration 324 may be a 60 function of the out-of-limit parameter 312. In an advantageous embodiment, the duration 324 relates to, or is a function of, the treatment time for the alarm-triggering parameter so as to avoid nuisance alarms while maintaining alarm integrity.

FIG. 4 illustrates an alarm suspend embodiment 400 that operates independently for each measured parameter that

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can trigger an alarm. An alarm is initially off 410. The alarm remains off as long as the parameter is within its set limits 412. If a parameter is measured outside of its set limits 414, an alarm is triggered 420. The alarm may audible, visual or both audible and visual. A user can request to silence the alarm by pressing an alarm silence button 144 (FIG. 1), for example. The silence request 422 suspends the alarm 430 which turns off audible alarms but, in an embodiment, does not deactivate visual alarms. The audible alarm remains suspended 430 for a predetermined duration 432. When the suspend duration has passed, the alarm suspend expires 434 and audible alarms are once again activated 420. The alarm remains on 428 until the triggering parameter is within limits 424 or a user once again requests silence 422. The alarm suspend 430 deactivates if the measured parameter becomes within limits 438, such as when the patient condition improves, or if no physiological data is detected 439, such as no sensor, sensor off, no cable or malfunctioning sensor situations, to name a few. Also, if the measured parameter changes during the alarm suspend 430 by a sufficient outof-limit amount, an override 436 reactivates the audible alarms 420.

In an alarm suspend system embodiment, parameters are classified according to the typical time it takes for medical treatment to transition an out-of-limit measurement to a within-limit measurement. Suspend durations 324 (FIG. 3) are set accordingly. For example, in a two-tier embodiment, relatively slow treatment parameters, such as HbMet, HbCO, Hbt and PVI, are assigned relatively long suspend durations. Similarly, relatively fast treatment parameters, such as SpO2 and PR, are assigned relatively short suspend durations. In an embodiment, the alarm suspend duration is adjustable for each individual parameter, including 2, 5, 10, 15, 20, 25 and 30 minutes for slow treatment parameters, with a default of 15 minutes; and 30, 60, 90 and 120 seconds for fast treatment parameters, with a default of 120 seconds. These alarm features are only active when alarm limits have been set. Other alarm features apply to both slow treatment and fast treatment parameters. For example, an alarm delay of 0, 5, 10 or 15 seconds applies to all enabled parameters.

In an embodiment, an override **436** occurs if slow treatment parameters such as HbCO, HbMet or PVI increase or Hbt decreases by a certain unit change during the alarm suspend duration. The unit change is adjustable for each parameter, such as from 1-15 in increments of 1. TABLE 1 shows a default embodiment of override unit changes for these parameters.

TABLE 1

Override Unit Changes for Selected Parameters							
Parameter	Unit Change	Direction					
НЬСО	5	Increase					
HbMet	2	Increase					
Hbt	2	Decrease					
PVI	OFF	Increase					

FIG. 5 illustrates an alarm suspend window 500 that provides a "pop-up" display so that a monitor user may manually enter an alarm suspend duration. The alarm suspend window 500 appears as a portion of a monitor display 501, such as the front panel display 120 (FIG. 1) described above. The pop-up window 500 responds to a suspend request, such as a silence button 144 (FIG. 1) press. The alarm suspend window 500 has a window identifier 502 and one or more parameter subsections 510, 520. Each param-

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eter subsection 510, 520 has a parameter identifier 512, 522 and corresponding suspend duration options 514, 524. In an embodiment, specific suspend times are selected via monitor touch keys 130 (FIG. 1) as guided by corresponding touch key icons 560. Selected suspend times are highlighted or 5 otherwise identified and entered, also via a touch key 130 (FIG. 1). In an alternative embodiment, the monitor display is a touch screen and alarm suspend times are directly entered by a finger press on a specific duration "virtual button" 514, 524. Once one or more suspend durations are 10 entered, the pop-up window 500 disappears from the display 501. The alarm suspend window 500 advantageously allows a user to quickly choose an appropriate alarm suspend duration for the situation at hand, rather than relying on a predetermined or default duration.

An alarm suspend system is described above with respect to alarms triggered by measured parameters and limits associated with those measured parameters. Limits may correspond to levels of a measured parameter, such as a percentage oxygen saturation to name but one example. 20 Limits may also correspond to trends of a measured parameter, such as a rate-of-change of oxygen saturation, for example. Limits may also correspond to patterns in a measured parameter or a comparison of one measured parameter with another measured parameter, as further examples.

An alarm suspend system is described above with respect to a two-tier grouping of parameters, such as slow treatment and fast treatment parameters and alarm suspend durations associated with those groups. Groupings of parameters with respect to alarm suspend durations may be multi-tier, such as slow, medium and fast treatment parameters, to name but one example.

An alarm suspend system has been disclosed in detail in connection with various embodiments. These embodiments are disclosed by way of examples only and are not to limit 35 the scope of the claims that follow. One of ordinary skill in the art will appreciate many variations and modifications.

What is claimed is:

- 1. A physiological measurement system comprising:
- a *noninvasive* physiological sensor [including: a plurality 40 of light emitting diodes] configured to [transmit wavelengths of light onto a tissue site of a patient; and at least one detector configured to measure an indication of the wavelengths of light after attenuation by tissue of the patient and] be positioned on a patient and output 45 a signal responsive [of the attenuated light] to a physiological condition of the patient; and
- one or more processors in communication with the *non-invasive* physiological sensor, the one or more processors configured to *electronically*:

process the signal;

responsive to processing the signal, determine a measurement of a physiological parameter based at least in part upon the signal;

determine that the measurement of the physiological 55 parameter satisfies an alarm activation threshold;

[receive, from a user, an indication of] *initiate* a parameter-specific alarm *delay or* suspension period of time corresponding to the physiological parameter, the parameter-specific alarm *delay or* suspension 60 period of time being [selected from] *one of* a plurality of parameter-specific alarm *delay or* suspension periods of time, the parameter-specific alarm *delay or* suspension period of time being different from at least one other parameter-specific alarm *delay or* suspension period of time corresponding to at least one other physiological parameter *for which*

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the one or more processors are configured to determine at least one measurement; [activate an alarm in response to determining that an alarm activation threshold has been satisfied by the physiological parameter measurement; receive an alarm suspension indication;] and

- [in response to receiving the alarm suspension indication, suspend the alarm for activate an alarm for the physiological parameter in response to expiration of an amount of delay or suspension associated with the [indicated] parameter-specific alarm delay or suspension period of time.
- 2. The physiological measurement system of claim 1, wherein the one or more processors are further configured
 - provide a user interface to the user including at least a plurality of user-selectable elements, each of the [selectable] plurality of user-selectable elements corresponding to one of the plurality of parameter-specific alarm delay or suspension periods of time.
- 3. The physiological measurement system of claim 2, wherein providing the user interface further includes: constructing a pop-up window for a display; and displaying the plurality of user-selectable elements in the pop-up window.
- **4.** The physiological measurement system of claim **3**, wherein the plurality of user-selectable elements are configured to allow a user to select a specific one of the plurality of parameter-specific alarm *delay or* suspension periods of time
- 5. The physiological measurement system of claim 4, wherein [the] a selected parameter-specific alarm *delay or* suspension period of time is selected by selection of one of the plurality of user-selectable elements.
- **6**. The physiological measurement system of claim **1**, wherein the one or more processors are further configured to:
 - associate [the] a selected parameter-specific alarm delay or suspension period of time [is] with the physiological parameter.
- 7. The physiological measurement system of claim 6, wherein the selected parameter-specific *alarm delay or suspension* period of time is stored in a memory device in communication with the one or more processors.
- **8**. The physiological measurement system of claim **1**, wherein the one or more processors are further configured to:

responsive to processing the signal, determine a measurement of a second physiological parameter [measurement] based at least in part upon the signal;

determine that the measurement of the second physiological parameter satisfies a second alarm activation threshold;

[receive, from the user, a second indication of] initiate a second parameter-specific alarm delay or suspension period of time corresponding to the second physiological parameter, the second parameter-specific alarm delay or suspension period of time being [selected from] one of a second plurality of parameter-specific alarm delay or suspension periods of time; [activate a second alarm in response to determining a second alarm activation threshold has been satisfied by the second physiological parameter measurement;] and

[in response to receiving the alarm suspension indication, suspend the second alarm for activate a second alarm for the second physiological parameter in response to expiration of an amount of delay or suspension asso-

- ciated with the [indicated] second parameter-specific alarm delay or suspension period of time.
- 9. The physiological measurement system of claim 8, wherein the one or more processors are further configured

provide a user interface to the user including at least a first plurality of user-selectable elements and a second plurality of user-selectable elements, wherein each of the first plurality of user-selectable elements corresponds to one of the plurality of parameter-specific alarm delay 10 or suspension periods of time, and each of the second plurality of user-selectable element corresponds to one of the second plurality of parameter-specific alarm delay or suspension periods of time.

10. The physiological measurement system of claim 9, 15 wherein the one or more processors are further configured

construct a pop-up window for a display; and display both the first and second plurality of user-selectable elements in the pop-up window.

- 11. The physiological measurement system of claim 10, wherein [the] a selected parameter-specific alarm delay or suspension period of time is selected by selection of one of the first plurality of user-selectable elements, and [the] a selected second parameter-specific alarm delay or suspen- 25 sion period of time is selected by selection of one of the second plurality of user-selectable elements.
- 12. The physiological measurement system of claim 11, wherein the at least one of the first plurality of parameterspecific alarm delay or suspension periods of time is differ- 30 ent from any of the second plurality of parameter-specific alarm delay or suspension periods of time.
- **13**. [An] A method of electronically delaying or suspending an alarm while an electronically calculated measurevation threshold, the measurement of the physiological parameter responsive to a signal from a noninvasive sensor positioned at a monitored patient, the method comprising: electronically processing a signal from a noninvasive

[measuring] responsive to processing the signal, electronically determining a first measurement of a first physiological parameter and a second measurement of a second physiological parameter using a patient monitoring device, the patient monitoring device including 45 a processor and a memory device [configured to store];

electronically storing, using the patient monitoring device, a first parameter-specific alarm delay or suspension period of time corresponding to the first physiological parameter and a second parameter-specific 50 alarm delay or suspension period of time corresponding to the second physiological parameter, the first parameter-specific alarm delay or suspension period of time being different from the second parameter-specific alarm delay or suspension period of time;

electronically determining, using the patient monitoring device, that the first measurement of the first physiological parameter satisfies a first alarm activation threshold;

[receiving, from a user, an indication of a] electronically 60 initiating, using the patient monitoring device, the first parameter-specific alarm delay or suspension period of time [corresponding to the physiological parameter, the parameter-specific alarm suspension period of time being selected from a plurality of parameter-specific 65 alarm suspension periods of time, the parameter-specific alarm suspension period of time being different

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from at least one other parameter-specific alarm suspension period of time corresponding to at least one other physiological parameter; activating an alarm in response to determining an alarm activation threshold has been satisfied by the physiological parameter measurement; receiving an alarm suspension indication];

[in response to receiving the alarm suspension indication, suspending the alarm for electronically activating, using the patient monitoring device, a first alarm for the first physiological parameter in response to expiration of a first amount of delay or suspension associated with the [indicated] first parameter-specific alarm delay or suspension period of time.

14. The method of claim 13, wherein the first alarm includes an audible component and a visual component, and wherein [suspending] activating the first alarm in response to expiration of the first amount of delay or suspension comprises [suspending] activating the audible component 20 [and not suspending the visual component].

15. The method of claim 13 further comprising: providing a user interface to the user including at least a plurality of user-selectable elements, each of the [selectable] plurality of user-selectable elements corresponding to one of [the] a plurality of parameterspecific alarm delay or suspension periods of time,

wherein the plurality of parameter-specific alarm delay or suspension periods of time comprise the first parameter-specific alarm delay or suspension period of time.

- **16**. The method of claim **15** further comprising: constructing a pop-up window for a display; and displaying the plurality of user-selectable elements in the pop-up window.
- 17. The method of claim 16, wherein [the] a selected ment of a physiological parameter satisfies an alarm acti- 35 parameter-specific alarm delay or suspension period of time is selected by selection of one of the plurality of userselectable elements.
 - 18. A physiological measurement system comprising:
 - a physiological sensor means for outputting a signal responsive to a [noninvasive measurement of attenuated light transmitted through a tissue site *physiologi*cal condition of a patient;
 - a memory configured to store a first alarm activation threshold; and
 - [a processing means] one or more processors in communication with the physiological sensor means and configured to:

process the signal;

responsive to processing the signal, determine a first measurement of [a] the first measured physiological parameter based at least in part upon the signal;

[receive, from a user, an indication of] initiate a first parameter-specific alarm delay or suspension period of time corresponding to the first measured physiological parameter, [the parameter-specific alarm suspension period of time being selected from a plurality of parameter-specific alarm suspension periods of time, the *first* parameter-specific alarm delay or suspension period of time being different from [at least one other] a second parameter-specific alarm delay or suspension period of time corresponding to [at least one other] a second measured physiological parameter for which the one or more processors are configured to determine a second measurement:

delay or suspend activation of an alarm for the first measured physiological parameter for the first

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parameter-specific alarm delay or suspension period of time while the first alarm activation threshold is satisfied by the measurement of the first measured physiological parameter; and

subsequent to delaying or suspending activation of the
alarm for the first parameter-specific alarm delay or
suspension period of time, activate [an] the alarm in
response to determining [an] the first alarm activation threshold [has been] is satisfied by the first
measurement of the first measured physiological
parameter [measurement; receive an alarm suspension indication; and in response to receiving the
alarm suspension indication, suspend the alarm for
the indicated parameter-specific alarm suspension
period of time].

19. The physiological measurement system of claim 18, wherein the [processing means is] one or more processors are further configured to:

responsive to processing the signal, determine [a] the second [physiological parameter] measurement based ²⁰ at least in part upon the signal;

[receive, from the user, a second indication of a] *initiate* the second parameter-specific alarm delay or suspension period of time [corresponding to the second physiological parameter, the second parameter-specific 25 alarm suspension period of time being selected from a second plurality of parameter-specific alarm suspension periods of time];

delay or suspend activation of a second alarm for the second measured physiological parameter for the second parameter-specific alarm delay or suspension period of time while a second alarm activation threshold is satisfied by the second measurement; and

subsequent to delaying or suspending activation of the second alarm for the second parameter-specific alarm delay or suspension period of time, activate [a] the second alarm [in response] responsive to determining [a] that the second alarm activation threshold [has been] is satisfied by the second [physiological parameter] measurement[; and

in response to receiving the alarm suspension indication, suspend the second alarm for the indicated second parameter-specific alarm suspension period of time].

20. The physiological measurement system of claim **19**, wherein the [processing means is] *one or more processors* ⁴⁵ *are* further configured to:

provide a user interface to the user including at least a first plurality of user-selectable elements and a second plurality of user-selectable elements, wherein each of the first plurality of user-selectable elements corresponds to one of [the] a first plurality of parameter-specific alarm delay or suspension periods of time, and each of the second plurality of user-selectable element corre-

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sponds to one of [the] a second plurality of parameterspecific alarm delay or suspension periods of time,

wherein the first plurality of parameter-specific alarm delay or suspension periods of time comprise the first parameter-specific alarm delay or suspension period of time, and the second plurality of parameter-specific alarm delay or suspension periods of time comprise the second parameter-specific alarm delay or suspension period of time.

21. The physiological measurement system of claim 20, wherein [the] a selected first parameter-specific alarm delay or suspension period of time is selected by selection of one of the first plurality of user-selectable elements, and [the] a selected second parameter-specific alarm delay or suspension period of time is selected by selection of one of the second plurality of user-selectable elements.

22. The physiological measurement system of claim 21, wherein at least one of the first plurality of parameter-specific alarm *delay or* suspension periods of time is different from any of the second plurality of parameter-specific alarm *delay or* suspension periods of time.

23. The physiological measurement system of claim 1, wherein the alarm comprises an audible alarm.

24. The physiological measurement system of claim 1, wherein the one or more processors are further configured to:

determine that the measurement of the physiological parameter satisfies a second alarm activation threshold different from the alarm activation threshold; and

in response to determining that the measurement of the physiological parameter satisfies the second alarm activation threshold, activate the alarm for the physiological parameter prior to expiration of the amount of delay or suspension associated with the first parameter-specific alarm delay or suspension period of time.

25. The physiological measurement system of claim 1, wherein the one or more processors are further configured to:

determine that a measurement of a second physiological parameter satisfies a second alarm activation threshold; and

in response to determining the measurement of the second physiological parameter satisfies the second alarm activation threshold, activate an alarm for the second physiological parameter prior to expiration of the amount of delay or suspension associated with the first parameter-specific alarm delay or suspension period of time.

26. The physiological measurement system of claim 1, wherein the physiological parameter comprises an oxygen saturation, and the at least one other physiological parameter comprises a pulse rate.

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Field of Classification Search

(54) ALARM SUSPEND SYSTEM

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ABSTRACT

An alarm suspend system utilizes an alarm trigger responsive to physiological parameters and corresponding limits on those parameters. The parameters are associated with both fast and slow treatment times corresponding to length of time it takes for a person to respond to medical treatment for out-of-limit parameter measurements. Audible and visual alarms respond to the alarm trigger. An alarm silence button is pressed to silence the audible alarm for a predetermined suspend time. The audible alarm is activated after the suspend time has lapsed. Longer suspend times are associated with slow treatment parameters and shorter suspend times are associated with fast treatment parameters.

24 Claims, 5 Drawing Sheets

250 - 210 FRONT-END DISPLAY CONDITIONER DIGITAL SIGNAL ROCESSO ALARMS NSTRUMENT EMITTER USER I/O RIVERS CONVERTERS - 230 - 288 ALARM SUSPEND FIRMWARE SENSOR MONITOR

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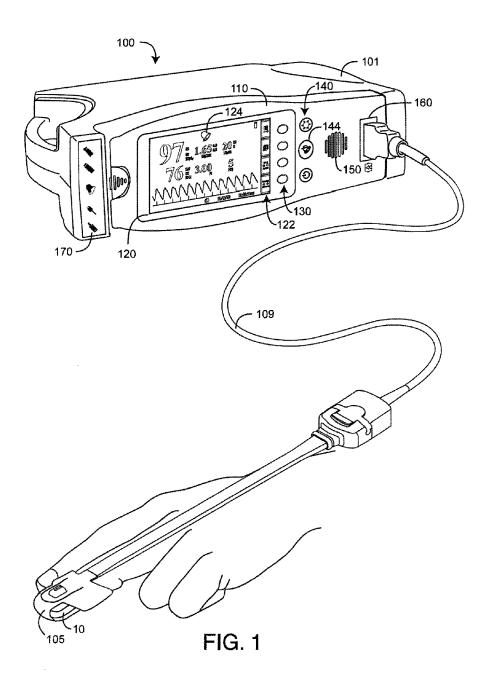
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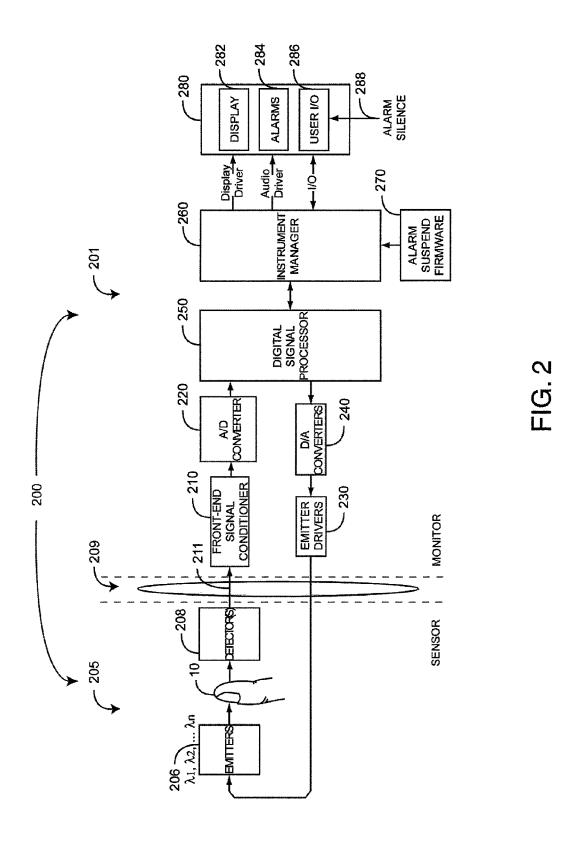
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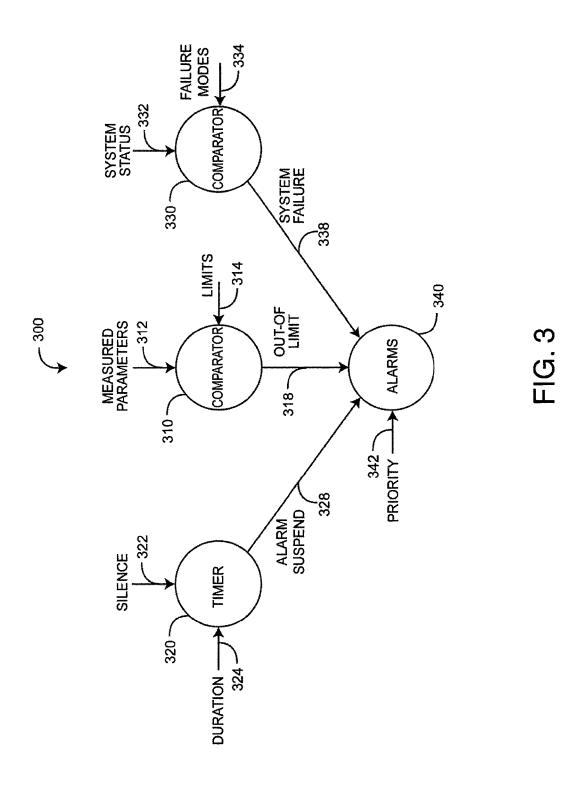
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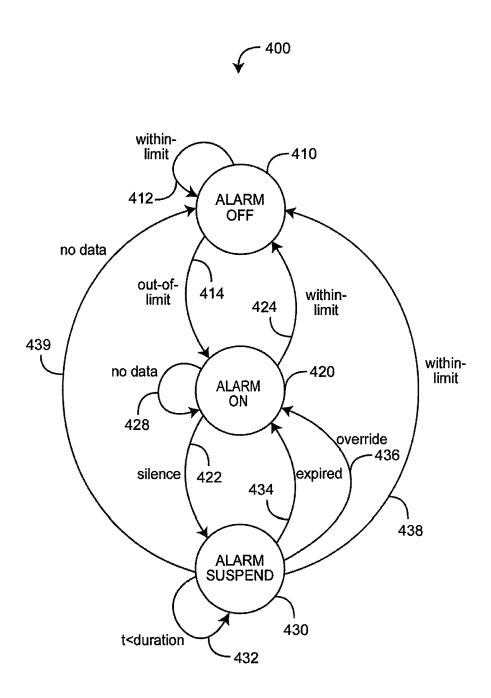


FIG. 4

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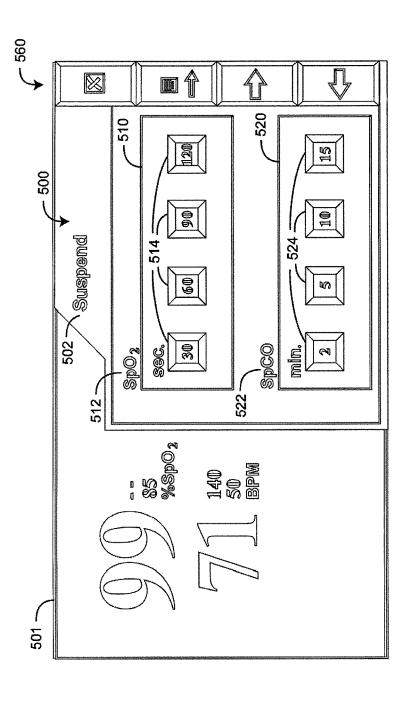


FIG. 5

1 ALARM SUSPEND SYSTEM

Matter enclosed in heavy brackets [] appears in the original patent but forms no part of this reissue specification; matter printed in italics indicates the additions made by reissue; a claim printed with strikethrough indicates that the claim was canceled, disclaimed, or held invalid by a prior post-patent action or proceeding.

CROSS-REFERENCE TO RELATED APPLICATIONS

This [application] is an application for reissue of U.S. Pat. No. 9,153,121, issued on Oct. 6, 2015 and titled "Alarm 15 Suspend System," which is a continuation of U.S. patent application Ser. No. 14/036,496, filed Sep. 25, 2013 and titled "Alarm Suspend System," which is a continuation of U.S. patent application Ser. No. 13/476,725, filed May 21, 2012 and titled "Alarm Suspend System," which is a con- 20 tinuation of U.S. patent application Ser. No. 12/510,982 filed Jul. 28, 2009 and titled "Alarm Suspend System," which claims priority benefit under 35 U.S.C. § 119(e) to U.S. Provisional Patent Application Ser. No. 61/084,615, filed Jul. 29, 2008, titled "Alarm Management System;" more 25 than one reissue application has been filed for the reissue of U.S. Pat. No. 9,153,121, including U.S. patent application Ser. No. 15/583,948 (the present application), U.S. patent application Ser. No. 15/583,922, and U.S. patent application Ser. No. 15/583,935.["] All of the above-referenced appli-30 cations are hereby incorporated by reference herein in their entireties.

BACKGROUND

Pulse oximetry for measuring constituents of circulating blood has achieved acceptance in a wide variety of medical applications, including surgical wards, intensive care and neonatal units, general wards, home care, physical training, and virtually all types of monitoring scenarios. A pulse 40 oximeter generally includes a two-wavelength optical sensor applied to a patient, a monitor for processing sensor signals and displaying results and a patient cable electrically interconnecting the sensor and the monitor. The monitor typically provides a numerical readout of physiological parameters 45 such as oxygen saturation (SpO₂) and pulse rate (PR). Advanced physiological monitors utilize multiple wavelength sensors and enhanced measurement capabilities to provide readouts of additional parameters, such as carboxyhemoglobin (HbCO), methemoglobin (HbMet) and total 50 hemoglobin (Hbt).

Pulse oximeters capable of reading through motion induced noise are disclosed in at least U.S. Pat. Nos. 6,770,028, 6,658,276, 6,650,917, 6,157,850, 6,002,952, 5,769,785 and 5,758,644; low noise pulse oximetry sensors 55 are disclosed in at least U.S. Pat. Nos. 6,088,607 and 5,782,757; all of which are assigned to Masimo Corporation, Irvine, Calif. ("Masimo") and are incorporated by reference herein.

Physiological monitors and corresponding multiple wavelength optical sensors are described in at least U.S. patent application Ser. No. 11/367,013, filed Mar. 1, 2006 and titled Multiple Wavelength Sensor Emitters and U.S. patent application Ser. No. 11/366,208, filed Mar. 1, 2006 and titled Noninvasive Multi-Parameter Patient Monitor, both 65 assigned to Masimo Laboratories, Irvine, Calif. (Masimo Labs) and both incorporated by reference herein.

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Further, physiological monitoring systems that include low noise optical sensors and pulse oximetry monitors, such as any of LNOP® adhesive or reusable sensors, SofTouchTM sensors, Hi-Fi TraumaTM or BlueTM sensors; and any of Radical®, SatShareTM, Rad-9TM, Rad-5TM, Rad-5TM, Rad-5TM or PPO+TM Masimo SET® pulse oximeters, are all available from Masimo. Physiological monitoring systems including multiple wavelength sensors and corresponding noninvasive blood parameter monitors, such as RainbowTM adhesive and reusable sensors and RAD-57TM and Radical-7TM monitors for measuring SpO₂, pulse rate (PR), perfusion index (PI), pleth variability index (PVI), signal quality, HbCO and HbMet among other parameters are also available from Masimo.

SUMMARY OF THE INVENTION

Monitor alarms are triggered by out-of-limit parameters and system failures, the latter including monitor or sensor failures or improper sensor placement, to name a few. Alarms can be visual, audible or both. Alarms can also have different levels of priority, which are reflected in the type of visual and audible alarms. In an embodiment, parameters exceeding limits such as low SpO₂, high HbCO, high HbMet and low and high BPM trigger high priority alarms. System failures due to sensor off, no sensor or defective sensor also trigger high priority alarms. Parameters exceeding limits such as high SpO₂, low and high PI, low and high PVI, for example, trigger medium priority alarms. Parameters exceeding limits such as low HbCO and low HbMet along with a system low battery indication are examples of low priority alarms.

An audible alarm may be temporarily suspended by pressing an alarm silence button so as to prevent unnecessary disturbance to the patient and distraction of the caregiver. During alarm suspension, visual alarms remain active. If an alarm condition persists after a predetermined alarm suspend period, the audible alarm resumes. The alarm suspend period is typically long enough to give a caregiver sufficient time to intervene with appropriate patient treatment yet short enough to ensure that patient health is not endangered if intervention is ineffective. For conventional pulse oximetry, an alarm suspend may be, for example, a maximum of 120 seconds.

Alarm suspension on advanced blood parameter monitors is problematic. With conventional pulse oximetry, treatment for abnormal parameter measurements can be quickly applied and a patient response is typically fast. For example, a treatment for low oxygen saturation is the application of an oxygen mask or an increase in oxygen flow. By contrast, the duration of treatment for parameters measured by advanced monitors is highly dependent on the alarm-triggering parameter. For example, the treatment for high methemoglobin is the injection of methylene blue, and the patient response to such an injection is slow. When patient treatment time exceeds the maximum alarm suspend period, an audible alarm will constantly reactivate. Thus, a single alarm suspend duration for all parameters is inadequate to cope with the many different types of parameters measured by advanced monitors.

One aspect of an alarm suspend system for silencing the alarms is an alarm trigger responsive to any of various parameters and predetermined limits corresponding to the parameters, where the parameters are partitioned according to treatment time, i.e. the relative length of time it takes for a person to respond to medical treatment for a parameter measurement outside of the predetermined limits. An

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audible alarm is responsive to the alarm trigger. An alarm silence button is actuated so as to suspend the audible alarm. A timer tracks the duration of the suspended alarm and is initiated by actuation of an alarm silence button. The timer retriggers the audible alarm after the timed duration has 5 lapsed/expired. In an embodiment, a long duration suspend time is associated with slow treatment parameters and a short duration suspend time is associated with fast treatment parameters. Fast treatment parameters may include, for example, parameters relating to normal blood hemoglobin 10 constituents and slow treatment parameters may include parameters relating to abnormal blood hemoglobin constitu-

In various embodiments, a short duration suspend time is less than or equal to about two minutes and a long duration 15 measurement system utilizing an alarm suspend system; suspended time is greater than about two minutes. A default duration associated with the fast treatment parameters is about two minutes and a default duration associated with the slow treatment parameters is about fifteen minutes. The alarm suspend system may also have an alarm suspend 20 override responsive to a predetermined unit change in the parameter triggering a suspended alarm. The override results in reactivation of the suspended alarm. A physiological monitor having an alarm suspend system may also have a pop-up window that appears on the monitor display in 25 response to actuation of the silence button, where the pop-up window presents a choice of alarm suspend durations.

Another aspect of an alarm suspend system is a partition of measured parameters into at least a first group and a second group. An audible alarm is triggered if at least one 30 parameter is outside of predetermined limits. The audible alarm is suspended in response to a silence request. A first duration is associated with the first group and a second duration is associated with the second group. The audible alarm is reactivated after at least one of the first duration and 35 the second duration. The first duration may be set so as to generally correspond to a first range of treatment times for the first group of parameters. Likewise, the second duration may be set so as to generally correspond to a second range of treatment times for the second group of parameters, where 40 the first range of treatment times and the second range of treatment times are non-overlapping.

In various embodiments, suspended audible alarms are overridden if the triggering parameter has greater than a predetermined unit change before the suspended alarm 45 expires according to either the first duration or the second duration. The first and second groups are defined in relation to normal hemoglobin measurements abnormal hemoglobin measurements, respectively. The first duration is set to be less than or equal to two minutes and the second duration is 50 set to be greater than two minutes, with default durations of about two minutes corresponding to the first group and about fifteen minutes corresponding to the second group. In an embodiment, a pop-up window for a monitor display is constructed and the first duration and the second duration are 55 selected from a range of durations presented within the pop-up window.

A further aspect of an alarm suspend system deactivates an audible alarm for one of a short duration and a long duration according to the alarm-triggering parameter. A first 60 group of parameters is associated with the short duration and a second group of parameters is associated with the long duration. The first group and the second group are partitioned according to a fast treatment time and a short treatment time associated with the parameters. An override 65 reactivates the audible alarm if the trigger parameter changes more than a predetermine amount during the cor-

responding duration. In various embodiments, the first group comprises parameters related to the measurement of normal hemoglobin and the second group comprises parameters related to the measurement of abnormal hemoglobin. The long duration is greater than about 120 seconds and the short duration is less than or equal to about 120 seconds. A pop-up window for the display allows selection of the long duration and the short duration in response to the silence button.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of a physiological measurement system utilizing an alarm suspend system;

FIG. 2 is a detailed block diagram of a physiological

FIG. 3 is a flow diagram of an alarm suspend system embodiment;

FIG. 4 is a state diagram of an alarm suspend system embodiment; and

FIG. 5 is an illustration of an alarm suspend pop-up window.

DETAILED DESCRIPTION

FIG. 1 illustrates a physiological measurement system 100 that utilizes an alarm suspend system. The physiological measurement system 100 has a noninvasive sensor 105 attached to a tissue site ${\bf 10}$, a physiological monitor ${\bf 101}$, and an interface cable 109 interconnecting the monitor 101 and the sensor 105. The physiological measurement system 100 may incorporate pulse oximetry in addition to advanced features, such as a multiple wavelength sensor and advanced processes for determining physiological parameters other than or in addition to those of pulse oximetry, such as carboxyhemoglobin, methemoglobin and total hemoglobin, as a few examples.

The monitor 101 has a front panel 110 providing a display 120, touch keys 130, controls 140, a speaker 150, a sensor port 160 and status indicators 170. The display 120 shows parameter readouts, limits and waveforms among other items. The display 120 also has touch key icons 122 that indicate touch key 130 functions. The speaker 150 provides an audible alarm in response to physiological measurements that violate preset conditions, such as an out-of-limit parameter, as well as system failures, such as a low battery condition. The controls 140 include an alarm silence button 144 that is pressed to temporarily suspend out-of-limit parameter alarms and system alarms, such as low battery. The display 120 provides visual alarms, which include a bell-shaped alarm status indicator 124 that illuminates during an alarm condition and parameter readouts 210 and limits 220 that flash when parameters are out-of-limit. Status indicators 170 also provide visual alarms. When there are multiple alarm conditions, the parameter displays 202 indicate parameters with the highest alarm priority. Touch keys 130 and corresponding icons 122 include an alarm menu access button for setting alarm conditions, such as high or low alarm limits for SpO₂, HbCO, HbMet, PR and PI. The alarm silence button 144 is pressed to temporarily suspend audible alarms. Advantageously, an alarm suspend system provides a parameter-dependent variation in the alarm suspend duration, as described below, utilizing a common silence button or other suspend initiator.

FIG. 2 illustrates a physiological measurement system 200 including a physiological monitor 201, a sensor 205 and an interface cable 209. The sensor 205 is attached to a tissue site, such as a finger 10, and includes a plurality of emitters

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206 irradiating the tissue site 10 with multiple wavelengths of light. The sensor 205 also includes one or more detectors 208 capable of detecting the light after attenuation by the tissue site 10. The sensor 205 transmits optical radiation at wavelengths other than or including the red and infrared 5 wavelengths utilized in pulse oximeters. The monitor 201 inputs a corresponding sensor signal 211 and determines the relative concentrations of blood constituents other than or in addition to the "normal" blood hemoglobin constituents $\rm HbO_2$ and $\rm Hb$, including "abnormal" blood hemoglobin 10 constituents $\rm HbC_0$, $\rm HbMet$ and blood related parameters such as fractional oxygen saturation, total hemoglobin and blood glucose to name a few.

As shown in FIG. 2, the monitor 201 has a front-end signal conditioner 210, an A/D converter 220, emitter drivers 230, D/A converters 240 and a digital signal processor ("DSP") 250. In general, the emitter drivers 230 convert digital control signals, via the D/A converters 240, into analog drive signals capable of driving the sensor emitters 206. The front-end signal conditioner 210 converts, via the 20 A/D converter 220, composite analog intensity signal(s) from light sensitive detector(s) 208 into digital data input to the DSP 250. The emitter drivers 230 and front-end signal conditioner 210 communicate with the sensor 205 via the interface cable 209.

Also shown in FIG. 2, the monitor 201 has an instrument manager 260 and a user interface 280. The user interface 280 includes one or more displays 282, alarms 284 and user input/output (I/O) 286. The instrument manager 260 communicates with the DSP 250 to receive parameter data and 30 to present that data on the display 282. The instrument manager 260 may also store and display historical or trending data related to one or more of the measured parameters or combinations of the measured parameters. The instrument manager 260 also controls audible and visual alarms and 35 indicators 284. The instrument manager 260 responds to user-actuated keys and communicates with external devices via various I/O ports 286. Further, the instrument manager 260 executes alarm suspend firmware 270 so as to respond to an alarm silence button press 288, as described in detail 40 with respect to FIGS. 3-4.

FIG. 3 generally illustrates an alarm suspend system 300. Alarm triggers include system failures 338 and out-of-limit parameters 318. Triggered alarms 340 may be audible, visual or both, and may vary according to priority 342. 45 Audible alarms may be generated by a monitor front-panel-mounted speaker 150 (FIG. 1) and may vary in loudness, pitch and sound pattern. Visual alarms may include parameter labels, parameter numerics, symbols and status lights, which can flash and vary in color.

As shown in FIG. 3, measured parameters 312 are compared 310 to default or user-specified limits 314. An out-of-limit condition 318 triggers an alarm 340. An alarm suspend 328 is user-initiated by a silence request 322. This may be a press of a silence button 144 (FIG. 1) on a monitor 55 front panel 110 (FIG. 1). In an embodiment, the alarm suspend 328 silences audible alarms and modifies the display of visual alarms. The alarm suspend 328 is based on a timer 320, which ends the alarm suspend 328 after a predetermined duration 324. The duration 324 may be a 60 function of the out-of-limit parameter 312. In an advantageous embodiment, the duration 324 relates to, or is a function of, the treatment time for the alarm-triggering parameter so as to avoid nuisance alarms while maintaining alarm integrity.

FIG. 4 illustrates an alarm suspend embodiment 400 that operates independently for each measured parameter that

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can trigger an alarm. An alarm is initially off 410. The alarm remains off as long as the parameter is within its set limits 412. If a parameter is measured outside of its set limits 414, an alarm is triggered 420. The alarm may audible, visual or both audible and visual. A user can request to silence the alarm by pressing an alarm silence button 144 (FIG. 1), for example. The silence request 422 suspends the alarm 430 which turns off audible alarms but, in an embodiment, does not deactivate visual alarms. The audible alarm remains suspended 430 for a predetermined duration 432. When the suspend duration has passed, the alarm suspend expires 434 and audible alarms are once again activated 420. The alarm remains on 428 until the triggering parameter is within limits 424 or a user once again requests silence 422. The alarm suspend 430 deactivates if the measured parameter becomes within limits 438, such as when the patient condition improves, or if no physiological data is detected 439, such as no sensor, sensor off, no cable or malfunctioning sensor situations, to name a few. Also, if the measured parameter changes during the alarm suspend 430 by a sufficient outof-limit amount, an override 436 reactivates the audible alarms 420.

In an alarm suspend system embodiment, parameters are classified according to the typical time it takes for medical treatment to transition an out-of-limit measurement to a within-limit measurement. Suspend durations 324 (FIG. 3) are set accordingly. For example, in a two-tier embodiment, relatively slow treatment parameters, such as HbMet, HbCO, Hbt and PVI, are assigned relatively long suspend durations. Similarly, relatively fast treatment parameters, such as SpO2 and PR, are assigned relatively short suspend durations. In an embodiment, the alarm suspend duration is adjustable for each individual parameter, including 2, 5, 10, 15, 20, 25 and 30 minutes for slow treatment parameters, with a default of 15 minutes; and 30, 60, 90 and 120 seconds for fast treatment parameters, with a default of 120 seconds. These alarm features are only active when alarm limits have been set. Other alarm features apply to both slow treatment and fast treatment parameters. For example, an alarm delay of 0, 5, 10 or 15 seconds applies to all enabled parameters.

In an embodiment, an override **436** occurs if slow treatment parameters such as HbCO, HbMet or PVI increase or Hbt decreases by a certain unit change during the alarm suspend duration. The unit change is adjustable for each parameter, such as from 1-15 in increments of 1. TABLE 1 shows a default embodiment of override unit changes for these parameters.

TABLE 1

Override U	Override Unit Changes for Selected Parameters		
Parameter	Unit Change	Direction	
НЬСО	5	Increase	
HbMet	2	Increase	
Hbt	2	Decrease	
PVI	OFF	Increase	

FIG. 5 illustrates an alarm suspend window 500 that provides a "pop-up" display so that a monitor user may manually enter an alarm suspend duration. The alarm suspend window 500 appears as a portion of a monitor display 501, such as the front panel display 120 (FIG. 1) described above. The pop-up window 500 responds to a suspend request, such as a silence button 144 (FIG. 1) press. The alarm suspend window 500 has a window identifier 502 and one or more parameter subsections 510, 520. Each param-

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eter subsection 510, 520 has a parameter identifier 512, 522 and corresponding suspend duration options 514, 524. In an embodiment, specific suspend times are selected via monitor touch keys 130 (FIG. 1) as guided by corresponding touch key icons 560. Selected suspend times are highlighted or 5 otherwise identified and entered, also via a touch key 130 (FIG. 1). In an alternative embodiment, the monitor display is a touch screen and alarm suspend times are directly entered by a finger press on a specific duration "virtual button" 514, 524. Once one or more suspend durations are 10 entered, the pop-up window 500 disappears from the display 501. The alarm suspend window 500 advantageously allows a user to quickly choose an appropriate alarm suspend duration for the situation at hand, rather than relying on a predetermined or default duration.

An alarm suspend system is described above with respect to alarms triggered by measured parameters and limits associated with those measured parameters. Limits may correspond to levels of a measured parameter, such as a percentage oxygen saturation to name but one example. 20 to: Limits may also correspond to trends of a measured parameter, such as a rate-of-change of oxygen saturation, for example. Limits may also correspond to patterns in a measured parameter or a comparison of one measured parameter with another measured parameter, as further examples.

An alarm suspend system is described above with respect to a two-tier grouping of parameters, such as slow treatment and fast treatment parameters and alarm suspend durations associated with those groups. Groupings of parameters with respect to alarm suspend durations may be multi-tier, such as 30 slow, medium and fast treatment parameters, to name but one example.

An alarm suspend system has been disclosed in detail in connection with various embodiments. These embodiments are disclosed by way of examples only and are not to limit 35 the scope of the claims that follow. One of ordinary skill in the art will appreciate many variations and modifications.

What is claimed is:

- 1. A physiological measurement system comprising:
- a noninvasive physiological sensor [including: a plurality 40 of light emitting diodes configured to [transmit wavelengths of light onto a tissue site of a patient; and at least one detector configured to measure an indication of the wavelengths of light after attenuation by tissue of the patient and be positioned on a patient and output 45 a signal responsive [of the attenuated light] to a physiological condition of the patient; and
- one or more processors in communication with the noninvasive physiological sensor, the one or more processors configured to *electronically*:
 - determine a measurement of a physiological parameter based at least in part upon the signal;
 - determine whether an alarm condition exists by determining whether an activation threshold has been satisfied by the measurement of the physiological 55 parameter:
 - [receive, from a user, an indication of] access an alarm hold initiator for a parameter-specific alarm [suspension *hold* period of time corresponding to the physiological parameter, the parameter-specific alarm 60 [suspension] hold period of time being [selected from one of a plurality of parameter-specific alarm [suspension] hold periods of time, the parameterspecific alarm [suspension] hold period of time being different from at least one other parameter-specific 65 alarm [suspension] hold period of time corresponding to at least one other physiological parameter for

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- which the one or more processors are configured to determine at least one measurement;
- activate an alarm in response to determining that an alarm activation threshold has been satisfied by the physiological parameter measurement;
- receive determine that the alarm hold initiator indicates to hold an indication of an alarm suspension indication] for the alarm condition; [and]
- in response to [receiving] determining that the alarm hold initiator indicates to hold the indication of the alarm [suspension indication], [suspend] hold the indication of the alarm for the [indicated] parameterspecific alarm [suspension] hold period of time; and
- subsequent to the parameter-specific alarm hold period of time passing, activate the indication of the alarm while the measurement of the physiological parameter satisfies the activation threshold.
- 2. The physiological measurement system of claim 1, wherein the one or more processors are further configured
 - provide a user interface to the user including at least a plurality of user-selectable elements, each of the plurality of user-selectable elements corresponding to one of the plurality of parameter-specific alarm [suspension *hold* periods of time.
- 3. The physiological measurement system of claim 2, wherein providing the user interface further includes: constructing a pop-up window for a display; and displaying the plurality of user-selectable elements in the
 - pop-up window.
- 4. The physiological measurement system of claim 3, wherein the plurality of user-selectable elements are configured to allow a user to select a specific one of the plurality of parameter-specific alarm [suspension] hold periods of time.
- 5. The physiological measurement system of claim 4, wherein the a selected parameter-specific alarm suspension] hold period of time is selected by selection of one of the plurality of user-selectable elements.
- 6. The physiological measurement system of claim 1, wherein the one or more processors are further configured
 - associate [the] a selected parameter-specific alarm hold period of time [is] with the physiological parameter.
- 7. The physiological measurement system of claim 6, wherein the selected parameter-specific alarm hold period of time is stored in a memory device in communication with the one or more processors.
- 8. The physiological measurement system of claim 1, wherein the one or more processors are further configured
 - determine a measurement of a second physiological parameter [measurement] based at least in part upon the signal, the second physiological parameter being different from the physiological parameter;
 - determine whether a second alarm condition exists by determining whether a second activation threshold has been satisfied by the measurement of the second physiological parameter;
 - [receive, from the user,] access a second [indication of] alarm hold initiator for a second parameter-specific alarm [suspension] hold period of time corresponding to the second physiological parameter, the second parameter-specific alarm [suspension] hold period of time being [selected from] one of a second plurality of parameter-specific alarm suspension hold periods of time, the second parameter-specific alarm hold period

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- of time being different from the parameter-specific alarm hold period of time corresponding to the physiological parameter;
- [activate a second alarm in response to determining a second alarm activation threshold has been satisfied by 5 the second physiological parameter measurement] determine that the second alarm hold initiator indicates to hold an indication of a second alarm for the second alarm condition; [and]
- in response to [receiving] determining that the second 10 alarm hold initiator indicates to hold the indication of the second alarm [suspension indication], [suspend] hold the indication of the second alarm for the [indicated] second parameter-specific alarm [suspension] hold period of time; and
- subsequent to the second parameter-specific alarm hold period of time passing, activate the indication of the second alarm while the measurement of the second physiological parameter satisfies the second activation threshold.
- **9**. The physiological measurement system of claim **8**, wherein the one or more processors are further configured to:
 - provide a user interface to the user including at least a first plurality of user-selectable elements and a second plurality of user-selectable elements, wherein each of the first plurality of user-selectable elements corresponds to one of the plurality of parameter-specific alarm [suspension] hold periods of time, and each of the second plurality of user-selectable element corresponds to one of the second plurality of parameter-specific alarm [suspension] hold periods of time.
- 10. The physiological measurement system of claim 9, wherein the one or more processors are further configured to:
 - construct a pop-up window for a display; and display both the first and second plurality of user-selectable elements in the pop-up window.
- 11. The physiological measurement system of claim 10, wherein [the] a selected first parameter-specific alarm [sus-40 pension] hold period of time is selected by selection of one of the first plurality of user-selectable elements, and [the] a selected second parameter-specific alarm [suspension] hold period of time is selected by selection of one of the second plurality of user-selectable elements.
- 12. The physiological measurement system of claim 11, wherein the at least one of the [first] plurality of parameter-specific alarm [suspension] *hold* periods of time is different from any of the second plurality of parameter-specific alarm [suspension] *hold* periods of time.
 - 13. [An] A method comprising:
 - measuring a *first* physiological parameter and a second physiological parameter using a patient monitoring device, the patient monitoring device including a processor and a memory device [configured to store a 55 parameter-specific alarm suspension period of time];
 - [receiving] accessing, from [a user] the memory device,
 [an indication of] a first alarm hold initiator for a first
 parameter-specific alarm [suspension] hold period of
 time corresponding to the first physiological parameter 60
 and a second alarm hold initiator for a second parameter-specific alarm hold period of time corresponding
 to the second physiological parameter, [the parameter-specific alarm suspension period of time being selected
 from a plurality of parameter-specific alarm suspension 65
 periods of time,] the first parameter-specific alarm
 [suspension] hold period of time being different from

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- [at least one other] the second parameter-specific alarm [suspension] hold period of time [corresponding to at least one other physiological parameter; activating an alarm in response to determining an alarm activation threshold has been satisfied by the physiological parameter measurement];
- [receiving an] determining that the first alarm hold initiator indicates to hold a first indication of a first alarm [suspension indication] for a first alarm condition for the first physiological parameter; [and]
- in response to [receiving] determining that the first alarm hold initiator indicates to hold the first indication of the first alarm [suspension indication], [suspending] holding the first indication of the first alarm for the [indicated] first parameter-specific alarm [suspension] hold period of time; and
- subsequent to the first parameter-specific alarm hold period of time passing, activating the first indication of the first alarm.
- 14. The method of claim 13, wherein the *first* alarm includes an audible component and a visual component, and wherein [suspending] *holding the first indication of the first* alarm comprises [suspending] *holding* the audible component and not [suspending] *holding* the visual component.
 - 15. The method of claim 13 further comprising: providing a user interface to the user including at least a plurality of user-selectable elements, each of the *plurality of user*-selectable elements corresponding to one of [the] a plurality of parameter-specific alarm [suspension] *hold* periods of time,
 - wherein the plurality of parameter-specific alarm hold periods of time comprise the first parameter specific alarm hold period of time.
- **16**. The method of claim **15** further comprising: constructing a pop-up window for a display; and displaying the plurality of user-selectable elements in the pop-up window.
- 17. The method of claim 16, wherein [the] a selected parameter-specific alarm [suspension] hold period of time is selected by selection of one of the plurality of user-selectable elements.
 - 18. A physiological measurement system comprising:
 - a physiological sensor [means for outputting] configured to output a signal responsive to a [noninvasive measurement of attenuated light transmitted through a tissue site] physiological condition of a patient;
 - a memory configured to store a first alarm activation threshold; and
 - [a processing means] one or more processors in communication with the physiological sensor [means] and configured to:
 - determine a *first* measurement of [a] *the first measured* physiological parameter based at least in part upon the signal;
 - determine whether a first alarm condition exists by determining whether the first alarm activation threshold has been satisfied by the first measurement of the first measured physiological parameter;
 - [receive, from a user, an indication of a] access a first alarm hold initiator for a first parameter-specific alarm [suspension] hold period of time corresponding to the first measured physiological parameter. [the parameter-specific alarm suspension period of time being selected from a plurality of parameter-specific alarm suspension periods of time,] the first parameter-specific alarm [suspension] hold period of time being different from [at least one other] a

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second parameter-specific alarm [suspension] hold period of time corresponding to [at least one other] a second measured physiological parameter for which the one or more processors are configured to determine a second measurement;

[activate an alarm in response to determining an alarm activation threshold has been satisfied by the physiological parameter measurement;

receive an determine that the first alarm hold initiator indicates to hold activation of a first alarm [suspension indication] for the first alarm condition; [and]

in response to [receiving] determining that the first alarm hold initiator indicates to hold activation of the first alarm [suspension indication], [suspend] hold activation of the first alarm for the [indicated] first parameter-specific alarm [suspension] hold period of time; and

activate the first alarm.

19. The physiological measurement system of claim **18**, 20 wherein the [processing means is] *one or more processors are* further configured to:

determine [a] *the* second [physiological parameter] measurement based at least in part upon the signal;

determine whether a second alarm condition exists by ²⁵ determining whether a second alarm activation threshold has been satisfied by the second measurement;

[receive, from the user,] *access* a second [indication of a] *alarm hold initiator for the* second parameter-specific alarm [suspension] *hold* period of time [corresponding to the second physiological parameter, the second parameter-specific alarm suspension period of time being selected from a second plurality of parameter-specific alarm suspension periods of time; activate a second alarm in response to determining a second ³⁵ alarm activation threshold has been satisfied by the second physiological parameter measurement];

determine that the second alarm hold initiator indicates to hold activation of a second alarm for the second alarm condition: and

in response to [receiving] determining that the second alarm hold initiator indicates to hold activation of the second alarm [suspension indication], [suspend] hold

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activation of the second alarm for the [indicated] second parameter-specific alarm [suspension] hold period of time.

20. The physiological measurement system of claim 19, wherein the [processing means is] one or more processors are further configured to:

provide a user interface to the user including at least a first plurality of user-selectable elements and a second plurality of user-selectable elements, wherein each of the first plurality of user-selectable elements corresponds to one of [the] a first plurality of parameter-specific alarm [suspension] hold periods of time, and each of the second plurality of user-selectable [element] elements corresponds to one of [the] a second plurality of parameter-specific alarm [suspension] hold periods of time.

wherein the first plurality of parameter-specific alarm hold periods of time comprise the first parameterspecific alarm hold period of time, and the second plurality of parameter-specific alarm hold periods of time comprise the second parameter-specific alarm hold period of time.

21. The physiological measurement system of claim 20, wherein [the] a selected *first* parameter-specific alarm [suspension] *hold* period of time is selected by selection of one of the first plurality of user-selectable elements, and [the] a selected second parameter-specific alarm [suspension] *hold* period of time is selected by selection of one of the second plurality of user-selectable elements.

22. The physiological measurement system of claim 21, wherein at least one of the first plurality of parameter-specific alarm [suspension] *hold* periods of time is different from any of the second plurality of parameter-specific alarm [suspension] *hold* periods of time.

specific alarm suspension periods of time; activate a second alarm in response to determining a second alarm activation threshold has been satisfied by the alarm activation threshold has been satisfied by the according to the parameter specific alarm hold period of time.

23. The physiological measurement system of claim 1, wherein the one or more processors are further configured to modify a visual indicator for the parameter-specific alarm hold period of time.

24. The physiological measurement system of claim 1, wherein the physiological parameter comprises one of an oxygen saturation, a pulse rate, a perfusion index, a pleth variability index, a carboxyhemoglobin, a methemoglobin, or a total hemoglobin.

* * * * *

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(54) ARM MOUNTABLE PORTABLE PATIENT MONITOR

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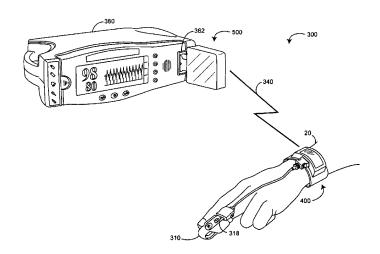
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(57) ABSTRACT

An arm mountable portable patient monitoring device configured to receive physiological information from a plurality of sensors attached to a patient via wired connections for on-patient monitoring of parameter measurements and wireless transmission of parameter measurements to separate monitoring devices. The arm mountable portable patient monitoring device includes a housing, a strap, a display, a first sensor port positioned on a first side of the housing configured to face toward a hand of the patient when the housing is secured to the arm of the patient, second and third sensor ports configured to receive signals from additional sensor arrangements via a wired connections, one or more signal processing arrangements configured to cause to be displayed measurements of oxygen saturation and pulse rate, and a transmitter configured to wirelessly transmit information indicative of the measurements of oxygen saturation and pulse rate to a separate monitoring device.

22 Claims, 17 Drawing Sheets



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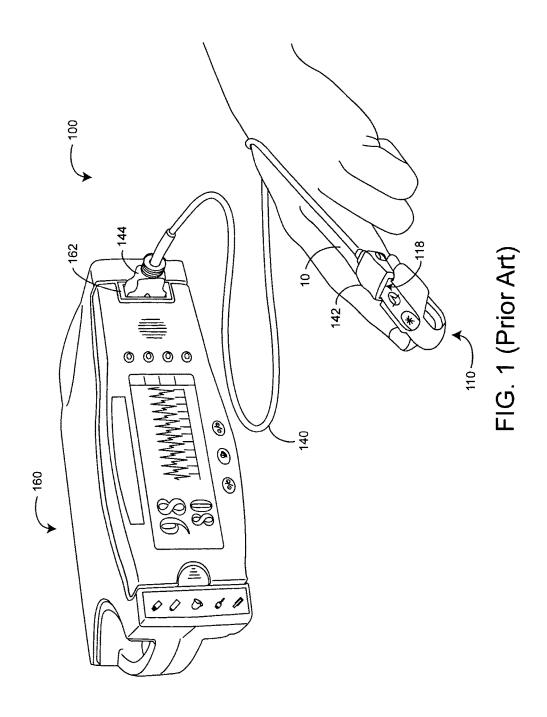
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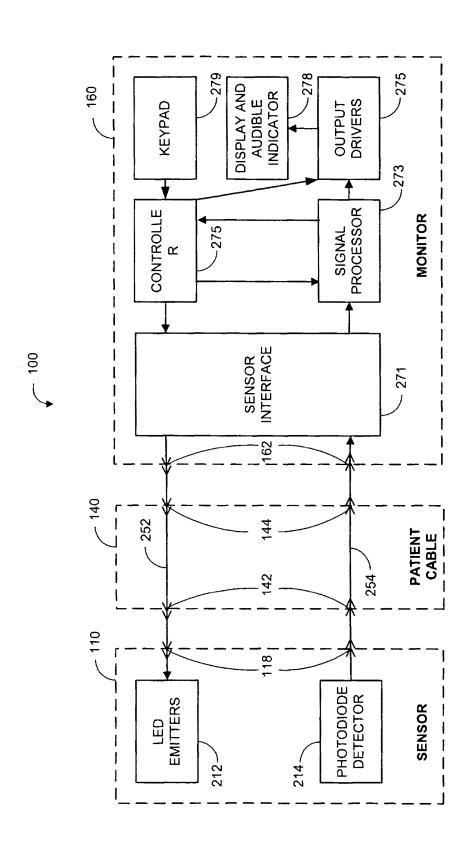
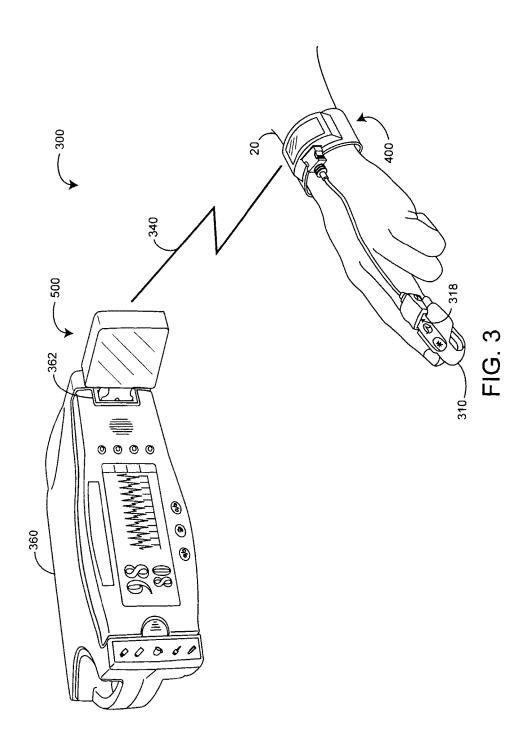


FIG. 2 (Prior Art)

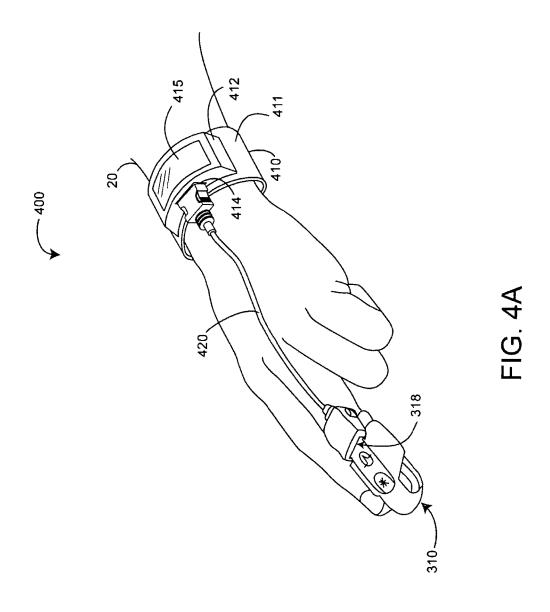
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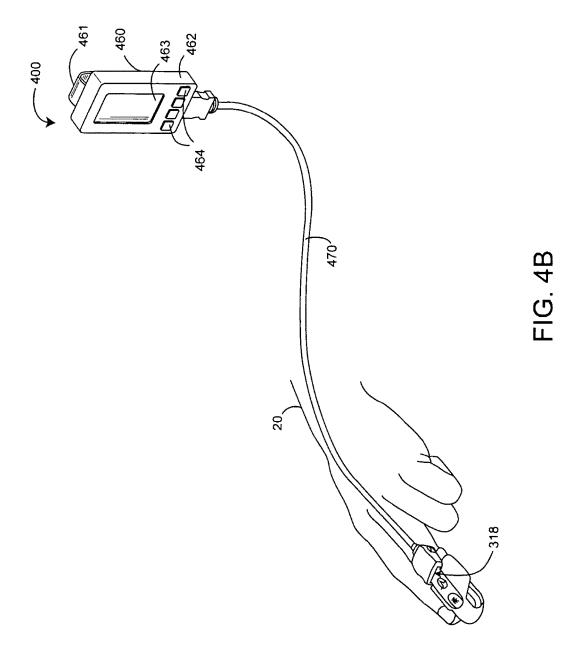
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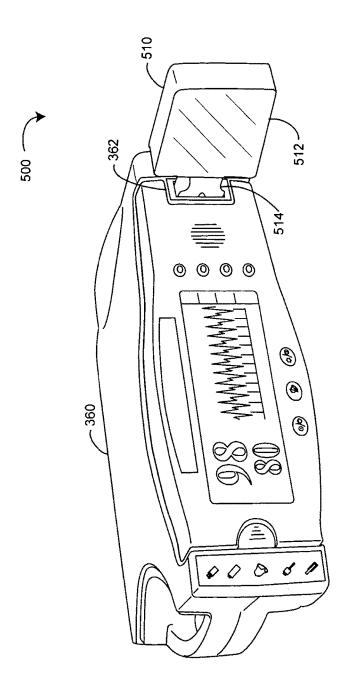
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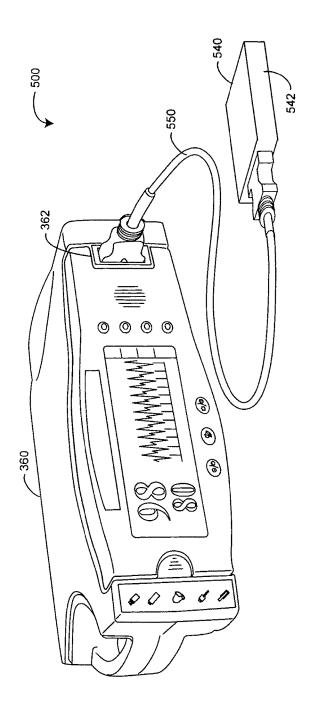
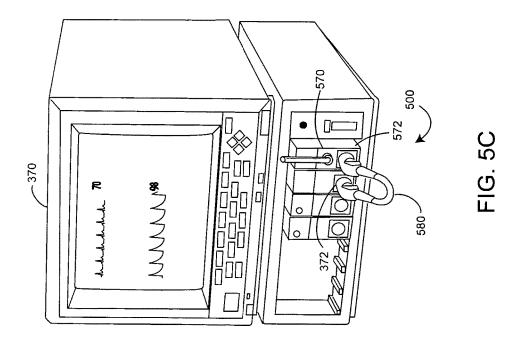


FIG. 5B

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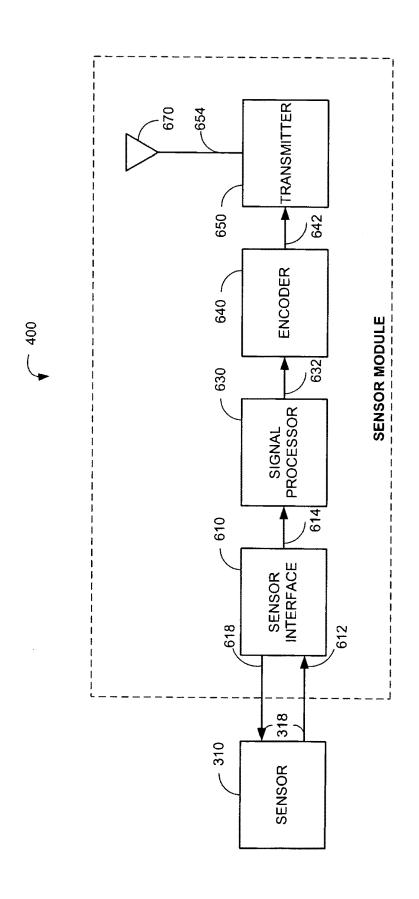
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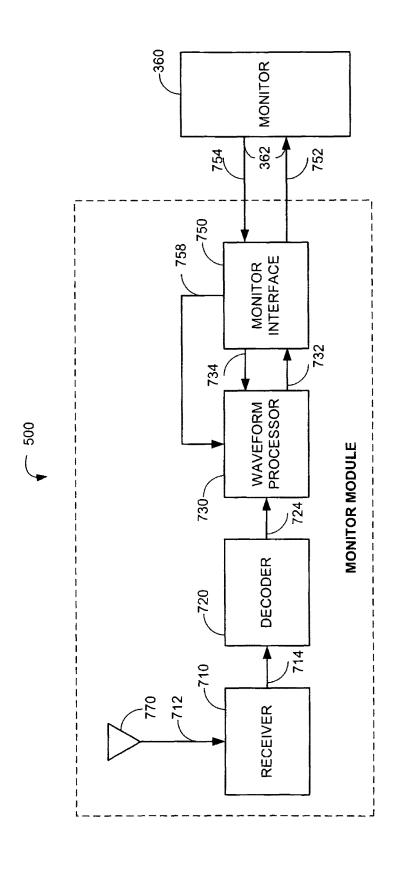
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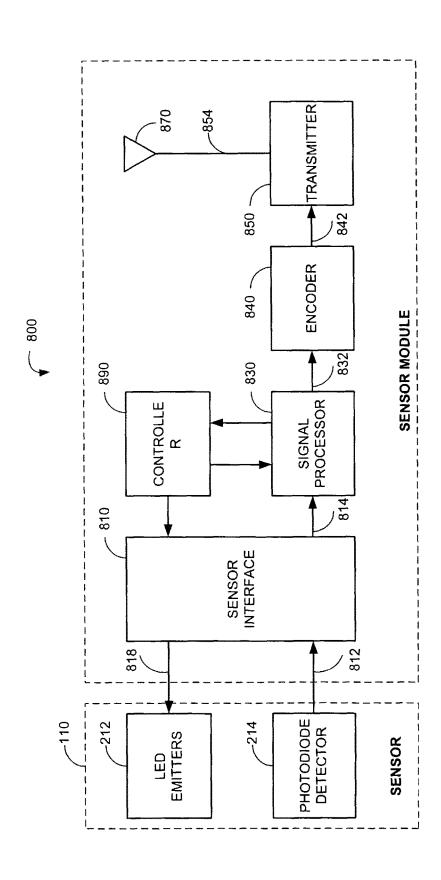
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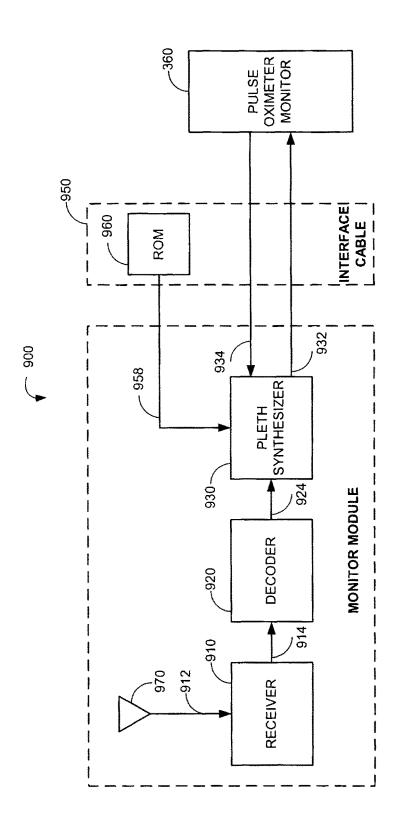
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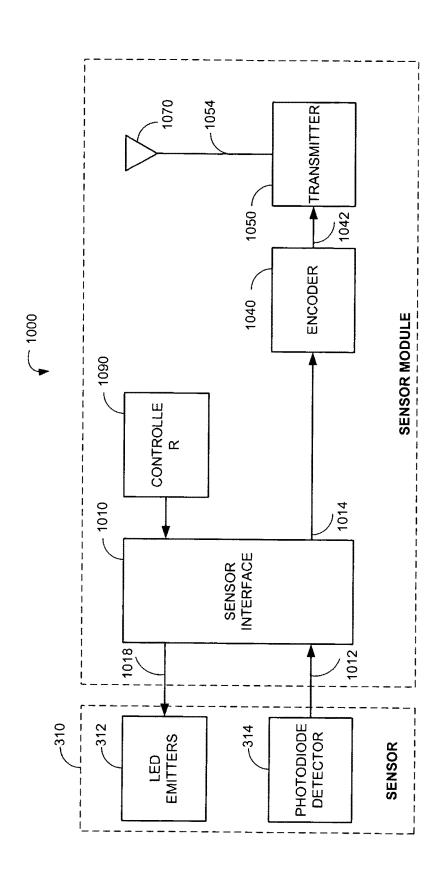


FIG. 10

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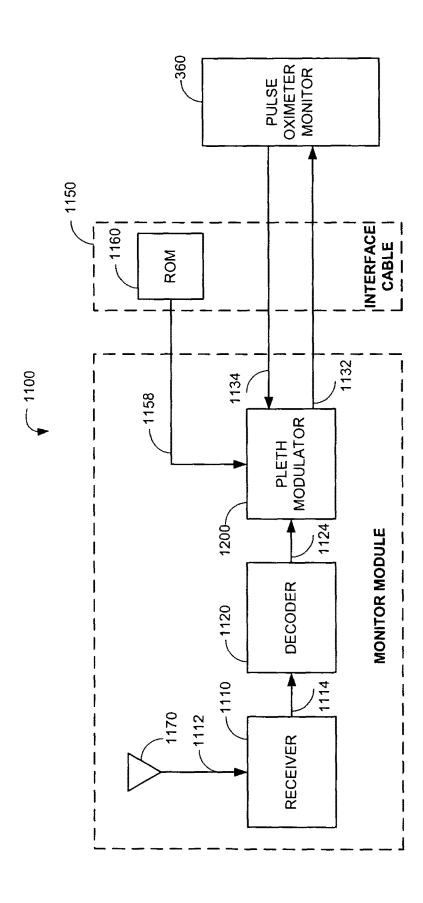
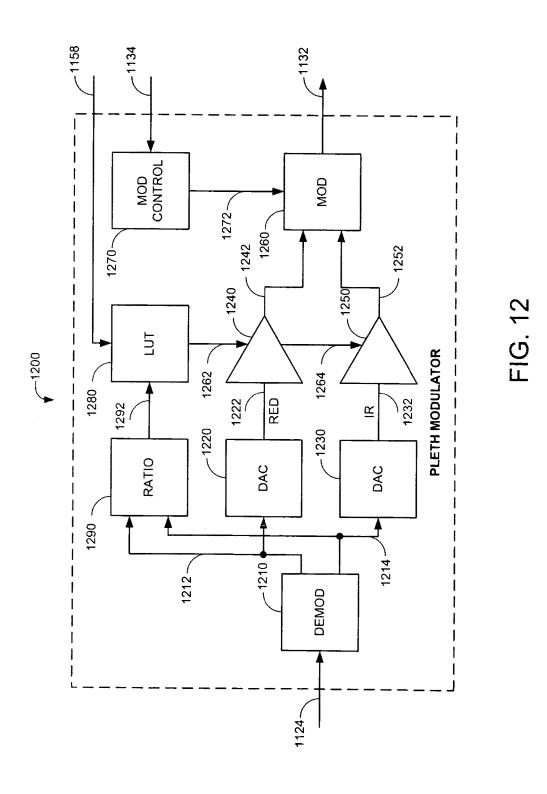


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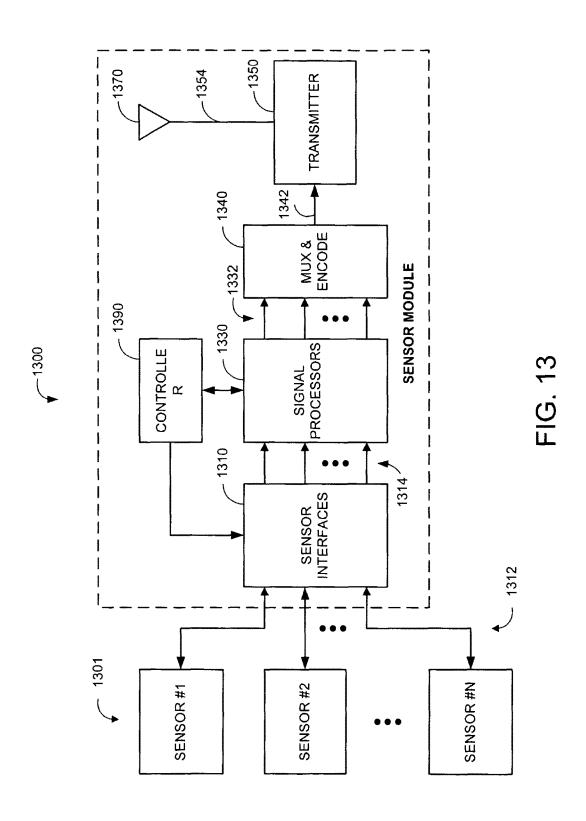
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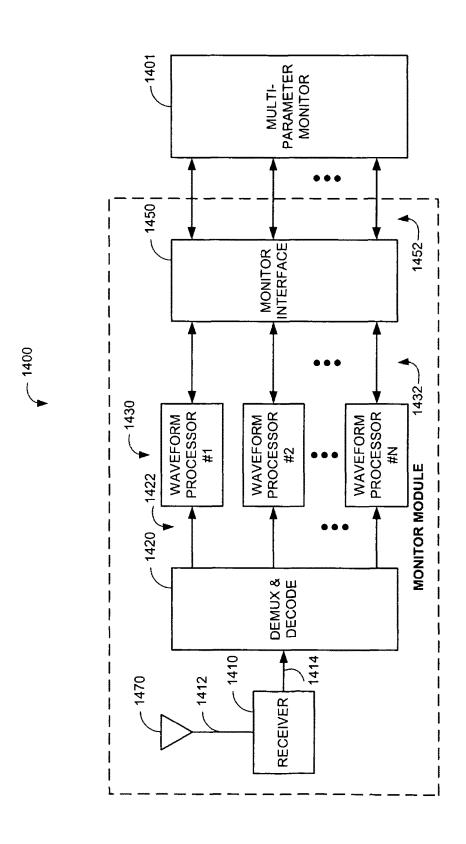


FIG. 14

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ARM MOUNTABLE PORTABLE PATIENT **MONITOR**

REFERENCE TO RELATED APPLICATION

The present application is a continuation of U.S. patent application Ser. No. 14/815,232, filed on Jul. 31, 2015, entitled "Physiological Measurement Communications Adapter," which is a continuation of U.S. patent application Ser. No. 14/217,788, filed on Mar. 18, 2014, entitled "Wrist-10" Mounted Physiological Measurement Device," now U.S. Pat. No. 9,113,832, which is a continuation of U.S. patent application Ser. No. 14/037,137, filed on Sep. 25, 2013, entitled "Physiological Measurement Communications Adapter," now U.S. Pat. No. 9,113,831, which is a continu- 15 name a few. ation of U.S. patent application Ser. No. 12/955,826, filed on Nov. 29, 2010, entitled "Physiological Measurement Communications Adapter," now U.S. Pat. No. 8,548,548, which is a continuation of U.S. patent application Ser. No. 11/417, ment Communications Adapter," now U.S. Pat. No. 7,844, 315, which claims priority benefit under 35 U.S.C. § 120 to, and is a continuation of, U.S. patent application Ser. No. 11/048,330, filed Feb. 1, 2005, entitled "Physiological Measurement Communications Adapter," now U.S. Pat. No. 25 7,844,314, which is a continuation of U.S. patent application Ser. No. 10/377,933, entitled "Physiological Measurement Communications Adapter," now U.S. Pat. No. 6,850,788, which claims priority benefit under 35 U.S.C. § 119(e) from U.S. Provisional Application No. 60/367,428, filed Mar. 25, 30 2002, entitled "Physiological Measurement Communications Adapter." The present application also incorporates the foregoing utility disclosures herein by reference.

BACKGROUND OF THE INVENTION

Patient vital sign monitoring may include measurements of blood oxygen, blood pressure, respiratory gas, and EKG among other parameters. Each of these physiological parameters typically requires a sensor in contact with a patient and 40 a cable connecting the sensor to a monitoring device. For example, FIGS. 1-2 illustrate a conventional pulse oximetry system 100 used for the measurement of blood oxygen. As shown in FIG. 1, a pulse oximetry system has a sensor 110, a patient cable 140 and a monitor 160. The sensor 110 is 45 typically attached to a finger 10 as shown. The sensor 110 has a plug 118 that inserts into a patient cable socket 142. The monitor 160 has a socket 162 that accepts a patient cable plug 144. The patient cable 140 transmits an LED drive signal 252 (FIG. 2) from the monitor 160 to the sensor 110 50 and a resulting detector signal 254 (FIG. 2) from the sensor 110 to the monitor 160. The monitor 160 processes the detector signal 254 (FIG. 2) to provide, typically, a numerical readout of the patient's oxygen saturation, a numerical readout of pulse rate, and an audible indicator or "beep" that 55 occurs in response to each arterial pulse.

As shown in FIG. 2, the sensor 110 has both red and infrared LED emitters 212 and a photodiode detector 214. The monitor 160 has a sensor interface 271, a signal processor 273, a controller 275, output drivers 276, a display 60 and audible indicator 278, and a keypad 279. The monitor 160 determines oxygen saturation by computing the differential absorption by arterial blood of the two wavelengths emitted by the sensor emitters 212, as is well-known in the art. The sensor interface 271 provides LED drive current 252 65 which alternately activates the red and IR LED emitters 212. The photodiode detector 214 generates a signal 254 corre2

sponding to the red and infrared light energy attenuated from transmission through the patient finger 10 (FIG. 1). The sensor interface 271 also has input circuitry for amplification, filtering and digitization of the detector signal 254. The signal processor 273 calculates a ratio of detected red and infrared intensities, and an arterial oxygen saturation value is empirically determined based on that ratio. The controller 275 provides hardware and software interfaces for managing the display and audible indicator 278 and keypad 279. The display and audible indicator 278 shows the computed oxygen status, as described above, and provides the pulse beep as well as alarms indicating oxygen desaturation events. The keypad 279 provides a user interface for setting alarm thresholds, alarm enablement, and display options, to

SUMMARY OF THE INVENTION

Conventional physiological measurement systems are 006, filed on May 3, 2006, entitled "Physiological Measure- 20 limited by the patient cable connection between sensor and monitor. A patient must be located in the immediate vicinity of the monitor. Also, patient relocation requires either disconnection of monitoring equipment and a corresponding loss of measurements or an awkward simultaneous movement of patient equipment and cables. Various devices have been proposed or implemented to provide wireless communication links between sensors and monitors, freeing patients from the patient cable tether. These devices, however, are incapable of working with the large installed base of existing monitors and sensors, requiring caregivers and medical institutions to suffer expensive wireless upgrades. It is desirable, therefore, to provide a communications adapter that is plug-compatible both with existing sensors and monitors and that implements a wireless link replacement 35 for the patient cable.

> An aspect of a physiological measurement communications adapter comprises a sensor interface configured to receive a sensor signal. A transmitter modulates a first baseband signal responsive to the sensor signal so as to generate a transmit signal. A receiver demodulates a receive signal corresponding to the transmit signal so as to generate a second baseband signal corresponding to the first baseband signal. Further, a monitor interface is configured to communicate a waveform responsive to the second baseband signal to a sensor port of a monitor. The waveform is adapted to the monitor so that measurements derived by the monitor from the waveform are generally equivalent to measurements derivable from the sensor signal. The communications adapter may further comprise a signal processor having an input in communications with the sensor interface, where the signal processor is operable to derive a parameter responsive to the sensor signal and where the first baseband signal is responsive to the parameter. The parameter may correspond to at least one of a measured oxygen saturation and a pulse rate.

> One embodiment may further comprise a waveform generator that synthesizes the waveform from a predetermined shape. The waveform generator synthesizes the waveform at a frequency adjusted to be generally equivalent to the pulse rate. The waveform may have a first amplitude and a second amplitude, and the waveform generator may be configured to adjusted the amplitudes so that measurements derived by the monitor are generally equivalent to a measured oxygen saturation.

In another embodiment, the sensor interface is operable on the sensor signal to provide a plethysmograph signal output, where the first baseband signal is responsive to the

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plethysmograph signal. This embodiment may further comprise a waveform modulator that modifies a decoded signal responsive to the second baseband signal to provide the waveform. The waveform modulator may comprise a demodulator that separates a first signal and a second signal from the decoded signal, an amplifier that adjusts amplitudes of the first and second signals to generate a first adjusted signal and a second adjusted signal, and a modulator that combines the first and second adjusted signals into the waveform. The amplitudes of the first and second signals may be responsive to predetermined calibration data for the sensor and the monitor.

An aspect of a physiological measurement communications adapter method comprises the steps of inputting a sensor signal at a patient location, communicating patient data derived from the sensor signal between the patient location and a monitor location, constructing a waveform at the monitor location responsive to the sensor signal, and providing the waveform to a monitor via a sensor port. The waveform is constructed so that the monitor calculates a parameter generally equivalent to a measurement derivable from the sensor signal.

FIG. 9 is configured

FIG. 10 configured

FIG. 11 in configured

FIG. 12 modulator;

FIG. 13 configured

FIG. 13 configured

In one embodiment, the communicating step may comprise the substeps of deriving a conditioned signal from the sensor signal, calculating a parameter signal from the con- 25 ditioned signal, and transmitting the parameter signal from the patient location to the monitor location. The constructing step may comprise the substep of synthesizing the waveform from the parameter signal. In an alternative embodiment, the communicating step may comprise the substeps of deriving 30 a conditioned signal from said sensor signal and transmitting the conditioned signal from the patient location to the monitor location. The constructing step may comprise the substeps of demodulating the conditioned signal and remodulating the conditioned signal to generate the waveform. 35 The providing step may comprise the substeps of inputting a monitor signal from an LED drive output of the sensor port, modulating the waveform in response to the monitor signal, and outputting the waveform on a detector input of the sensor port.

Another aspect of a physiological measurement communications adapter comprises a sensor interface means for inputting a sensor signal and outputting a conditioned signal, a transmitter means for sending data responsive to the sensor signal, and a receiver means for receiving the data. The 45 communications adapter further comprises a waveform processor means for constructing a waveform from the data so that measurements derived by a monitor from the waveform are generally equivalent to measurements derivable from the sensor signal, and a monitor interface means for communi- 50 cating the waveform to a sensor port of the monitor. The communications adapter may further comprise a signal processor means for deriving a parameter signal from the conditioned signal, where the data comprises the parameter signal. The waveform processor means may comprise a 55 means for synthesizing the waveform from the parameter signal. The data may comprise the conditioned signal, and the waveform processor means may comprise a means for modulating the conditioned signal in response to the monitor.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is an illustration of a prior art pulse oximetry system;

FIG. 2 is a functional block diagram of a prior art pulse oximetry system;

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FIG. 3 is an illustration of a physiological measurement communications adapter;

FIGS. 4A-B are illustrations of communications adapter sensor modules;

FIGS. **5**A-C are illustrations of communications adapter monitor modules;

FIG. **6** is a functional block diagram of a communications adapter sensor module;

FIG. 7 is a functional block diagram of a communications adapter monitor module;

FIG. **8** is a functional block diagram of a sensor module configured to transmit measured pulse oximeter parameters;

FIG. 9 is a functional block diagram of a monitor module configured to received measured pulse oximeter parameters;

FIG. 10 is a functional block diagram of a sensor module configured to transmit a plethysmograph;

FIG. 11 is a functional block diagram of a monitor module configured to receive a plethysmograph;

FIG. 12 is a functional block diagram of a waveform modulator:

FIG. 13 is a functional block diagram of a sensor module configured for multiple sensors; and

FIG. 14 is a functional block diagram of a monitor module configured for multiple sensors.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Overview

FIG. 3 illustrates one embodiment of a communications adapter. FIGS. 4-5 illustrate physical configurations for a communications adapter. In particular, FIGS. 4A-B illustrate sensor module configurations and FIGS. 5A-C illustrate monitor module configurations. FIGS. 6-14 illustrate communications adapter functions. In particular, FIGS. 6-7 illustrate general functions for a sensor module and a monitor module, respectively. FIGS. 8-9 functionally illustrate a communications adapter where derived pulse oximetry parameters, such as saturation and pulse rate are transmitted between a sensor module and a monitor module. Also, FIGS. 10-12 functionally illustrate a communications adapter where a plethysmograph is transmitted between a sensor module and a monitor module. FIGS. 13-14 functionally illustrate a multiple-parameter communications adapter.

FIG. 3 illustrates a communications adapter 300 having a sensor module 400 and a monitor module 500. The communications adapter 300 communicates patient data derived from a sensor 310 between the sensor module 400, which is located proximate a patient 20 and the monitor module 500, which is located proximate a monitor 360. A wireless link 340 is provided between the sensor module 400 and the monitor module 500, replacing the conventional patient cable, such as a pulse oximetry patient cable 140 (FIG. 1). Advantageously, the sensor module 400 is plug-compatible with a conventional sensor 310. In particular, the sensor connector 318 connects to the sensor module 400 in a similar manner as to a patient cable. Further, the sensor module 400 outputs a drive signal to the sensor 310 and inputs a sensor signal from the sensor 310 in an equivalent manner as a conventional monitor 360. The sensor module 400 may be battery powered or externally powered. External power may be for recharging internal batteries or for powering the sensor module during operation or both.

As shown in FIG. 3, the monitor module 500 is advantageously plug-compatible with a conventional monitor 360. In particular, the monitor's sensor port 362 connects to the

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monitor module 500 in a similar manner as to a patient cable, such as a pulse oximetry patient cable 140 (FIG. 1). Further, the monitor module 500 inputs a drive signal from the monitor 360 and outputs a corresponding sensor signal to the monitor 360 in an equivalent manner as a conventional sensor 310. As such, the combination sensor module 400 and monitor module 500 provide a plug-compatible wireless replacement for a patient cable, adapting an existing wired physiological measurement system into a wireless physiological measurement system. The monitor module 500 may be battery powered, powered from the monitor, such as by tapping current from a monitor's LED drive, or externally powered from an independent AC or DC power source.

Although a communications adapter **300** is described herein with respect to a pulse oximetry sensor and monitor, one of ordinary skill in the art will recognize that a communications adapter may provide a plug-compatible wireless replace for a patient cable that connects any physiological sensor and corresponding monitor. For example, a communications adapter **300** may be applied to a biopotential sensor, a non-invasive blood pressure (NIBP) sensor, a respiratory rate sensor, a glucose sensor and the corresponding monitors, to name a few.

Sensor Module Physical Configurations

FIGS. 4A-B illustrate physical embodiments of a sensor module 400. FIG. 4A illustrates a wrist-mounted module 410 having a wrist strap 411, a case 412 and an auxiliary cable 420. The case 412 contains the sensor module electronics, which are functionally described with respect to 30 FIG. 6, below. The case 412 is mounted to the wrist strap 411, which attaches the wrist-mounted module 410 to a patient 20. The auxiliary cable 420 mates to a sensor connector 318 and a module connector 414, providing a wired link between a conventional sensor 310 and the 35 wrist-mounted module 410. Alternatively, the auxiliary cable 420 is directly wired to the sensor module 400. The wrist-mounted module 410 may have a display 415 that shows sensor measurements, module status and other visual indicators, such as monitor status. The wrist-mounted mod- 40 ule 410 may also have keys (not shown) or other input mechanisms to control its operational mode and characteristics. In an alternative embodiment, the sensor 310 may have a tail (not shown) that connects directly to the wristmounted module 410, eliminating the auxiliary cable 420. 45

FIG. 4B illustrates a clip-on module 460 having a clip 461, a case 462 and an auxiliary cable 470. The clip 461 attaches the clip-on module 460 to patient clothing or objects near a patient 20, such as a bed frame. The auxiliary cable 470 mates to the sensor connector 318 and functions 50 as for the auxiliary cable 420 (FIG. 4A) of the wrist-mounted module 410 (FIG. 4A), described above. The clip-on module 460 may have a display 463 and keys 464 as for the wrist-mounted module 410 (FIG. 4A). Either the wrist-mounted module 410 or the clip-on module 460 may 55 have other input or output ports (not shown) that download software, configure the module, or provide a wired connection to other measurement instruments or computing devices, to name a few examples.

Monitor Module Physical Configurations

FIGS. 5A-C illustrate physical embodiments of a monitor module 500. FIG. 5A illustrates a direct-connect module 510 having a case 512 and an integrated monitor connector 514. The case 512 contains the monitor module electronics, which are functionally described with respect to FIG. 7, 65 below. The monitor connector 514 mimics that of the monitor end of a patient cable, such as a pulse oximetry

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patient cable 140 (FIG. 1), and electrically and mechanically connects the monitor module 510 to the monitor 360 via the monitor's sensor port 362.

FIG. 5B illustrates a cable-connect module 540 having a case 542 and an auxiliary cable 550. The case 542 functions as for the direct-connect module 510 (FIG. 5A), described above. Instead of directly plugging into the monitor 360, the cable-connect module 540 utilizes the auxiliary cable 550, which mimics the monitor end of a patient cable, such as a pulse oximetry patient cable 140 (FIG. 1), and electrically connects the cable-connect module 540 to the monitor sensor port 362.

FIG. 5C illustrates a plug-in module 570 having a plug-in case 572 and an auxiliary cable 580. The plug-in case 572 is mechanically compatible with the plug-in chassis of a multiparameter monitor 370 and may or may not electrically connect to the chassis backplane. The auxiliary cable 580 mimics a patient cable and electrically connects the plug-in module 570 to the sensor port 372 of another plug-in device. A direct-connect module 510 (FIG. 5A) or a cable-connect module 540 (FIG. 5B) may also be used with a multiparameter monitor 370.

In a multiparameter embodiment, such as described with respect to FIGS. 13-14, below, a monitor module 500 may connect to multiple plug-in devices of a multiparameter monitor 370. For example, a cable-connect module 540 (FIG. 5B) may have multiple auxiliary cables 550 (FIG. 5B) that connect to multiple plug-in devices installed within a multiparameter monitor chassis. Similarly, a plug-in module 570 may have one or more auxiliary cables 580 with multiple connectors for attaching to the sensor ports 372 of multiple plug-in devices.

Communications Adapter Functions

FIGS. 6-7 illustrate functional embodiments of a communications adapter. FIG. 6 illustrates a sensor module 400 having a sensor interface 610, a signal processor 630, an encoder 640, a transmitter 650 and a transmitting antenna 670. A physiological sensor 310 provides an input sensor signal 612 at the sensor connector 318. Depending on the sensor 310, the sensor module 400 may provide one or more drive signals 618 to the sensor 310. The sensor interface 610 inputs the sensor signal 612 and outputs a conditioned signal 614. The conditioned signal 614 may be coupled to the transmitter 650 or further processed by a signal processor 630. If the sensor module configuration utilizes a signal processor 630, it derives a parameter signal 632 responsive to the sensor signal 612, which is then coupled to the transmitter 650. Regardless, the transmitter 650 inputs a baseband signal 642 that is responsive to the sensor signal 612. The transmitter 650 modulates the baseband signal 642 with a carrier to generate a transmit signal 654. The transmit signal 654 may be derived by various amplitude, frequency or phase modulation schemes, as is well known in the art. The transmit signal 654 is coupled to the transmit antenna 670, which provides wireless communications to a corresponding receive antenna 770 (FIG. 7), as described below.

As shown in FIG. 6, the sensor interface 610 conditions and digitizes the sensor signal 612 to generate the conditioned signal 614. Sensor signal conditioning may be performed in the analog domain or digital domain or both and may include amplification and filtering in the analog domain and filtering, buffering and data rate modification in the digital domain, to name a few. The resulting conditioned signal 614 is responsive to the sensor signal 612 and may be used to calculate or derive a parameter signal 632.

Further shown in FIG. 6, the signal processor 630 performs signal processing on the conditioned signal 614 to

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generate the parameter signal 632. The signal processing may include buffering, digital filtering, smoothing, averaging, adaptive filtering and frequency transforms to name a few. The resulting parameter signal 632 may be a measurement calculated or derived from the conditioned signal, such as oxygen saturation, pulse rate, blood glucose, blood pressure and EKG to name a few. Also, the parameter signal 632 may be an intermediate result from which the above-stated measurements may be calculated or derived.

As described above, the sensor interface 610 performs mixed analog and digital pre-processing of an analog sensor signal and provides a digital output signal to the signal processor 630. The signal processor 630 then performs digital post-processing of the front-end processor output. In alternative embodiments, the input sensor signal 612 and the output conditioned signal 614 may be either analog or digital, the front-end processing may be purely analog or purely digital, and the back-end processing may be purely analog or mixed analog or digital.

In addition, FIG. 6 shows an encoder 640, which translates a digital word or serial bit stream, for example, into the baseband signal 642, as is well-known in the art. The baseband signal 642 comprises the symbol stream that drives the transmit signal 654 modulation, and may be a 25 single signal or multiple related signal components, such as in-phase and quadrature signals. The encoder 640 may include data compression and redundancy, also well-known in the art.

FIG. 7 illustrates a monitor module 500 having a receive 30 antenna 770, a receiver 710, a decoder 720, a waveform processor 730 and a monitor interface 750. A receive signal 712 is coupled from the receive antenna 770, which provides wireless communications to a corresponding transmit antenna 670 (FIG. 6), as described above. The receiver 710 35 inputs the receive signal 712, which corresponds to the transmit signal 654 (FIG. 6). The receiver 710 demodulates the receive signal to generate a baseband signal 714. The decoder 720 translates the symbols of the demodulated baseband signal 714 into a decoded signal 724, such as a 40 digital word stream or bit stream. The waveform processor 730 inputs the decoded signal 724 and generates a constructed signal 732. The monitor interface 750 is configured to communicate the constructed signal 732 to a sensor port **362** of a monitor **360**. The monitor **360** may output a sensor 45 drive signal 754, which the monitor interface 750 inputs to the waveform processor 730 as a monitor drive signal 734. The waveform processor 730 may utilize the monitor drive signal 734 to generate the constructed signal 732. The monitor interface 750 may also provide characterization 50 information 758 to the waveform processor 730, relating to the monitor 360, the sensor 310 or both, that the waveform processor 730 utilizes to generate the constructed signal 732.

The constructed signal 732 is adapted to the monitor 360 so that measurements derived by the monitor 360 from the 55 constructed signal 732 are generally equivalent to measurements derivable from the sensor signal 612 (FIG. 6). Note that the sensor 310 (FIG. 6) may or may not be directly compatible with the monitor 360. If the sensor 310 (FIG. 6) is compatible with the monitor 360, the constructed signal 60 732 is generated so that measurements derived by the monitor 360 from the constructed signal 732 are generally equivalent (within clinical significance) with those derivable directly from the sensor signal 612 (FIG. 6). If the sensor 310 (FIG. 6) is not compatible with the monitor 360, the 65 constructed signal 732 is generated so that measurements derived by the monitor 360 from the constructed signal 732

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are generally equivalent to those derivable directly from the sensor signal **612** (FIG. **6**) using a compatible monitor. Wireless Pulse Oximetry

FIGS. **8-11** illustrate pulse oximeter embodiments of a communications adapter. FIGS. **8-9** illustrate a sensor module and a monitor module, respectively, configured to communicate measured pulse oximeter parameters. FIG. **10-11** illustrate a sensor module and a monitor module, respectively, configured to communicate a plethysmograph signal. Parameter Transmission

FIG. 8 illustrates a pulse oximetry sensor module 800 having a sensor interface 810, signal processor 830, encoder 840, transmitter 850, transmitting antenna 870 and controller 890. The sensor interface 810, signal processor 830 and controller 890 function as described with respect to FIG. 2, above. The sensor interface 810 communicates with a standard pulse oximetry sensor 310, providing an LED drive signal 818 to the LED emitters 312 and receiving a sensor signal 812 from the detector 314 in response. The sensor interface 810 provides front-end processing of the sensor signal 812, also described above, providing a plethysmograph signal 814 to the signal processor 830. The signal processor 830 then derives a parameter signal 832 that comprises a real time measurement of oxygen saturation and pulse rate. The parameter signal 832 may include other parameters, such as measurements of perfusion index and signal quality. In one embodiment, the signal processor is an MS-5 or MS-7 board available from Masimo Corporation, Irvine, Calif.

As shown in FIG. 8, the encoder 840, the transmitter 850 and the transmitting antenna 870 function as described with respect to FIG. 6, above. For example, the parameter signal 832 may be a digital word stream that is serialized into a bit stream and encoded into a baseband signal 842. The baseband signal 842 may be, for example, two bit symbols that drive a quadrature phase shift keyed (QPSK) modulator in the transmitter 850. Other encodings and modulations are also applicable, as described above. The transmitter 850 inputs the baseband signal 842 and generates a transmit signal 854 that is a modulated carrier having a frequency suitable for short-range transmission, such as within a hospital room, doctor's office, emergency vehicle or critical care ward, to name a few. The transmit signal 854 is coupled to the transmit antenna 870, which provides wireless communications to a corresponding receive antenna 970 (FIG. 9), as described below.

FIG. 9 illustrates a monitor module 900 having a receive antenna 970, a receiver 910, a decoder 920, a waveform generator 930 and an interface cable 950. The receive antenna 970, receiver 910 and decoder 920 function as described with respect to FIG. 7, above. In particular, the receive signal 912 is coupled from the receive antenna 970, which provides wireless communications to a corresponding transmit antenna 870 (FIG. 8). The receiver 910 inputs the receive signal 912, which corresponds to the transmit signal 854 (FIG. 8). The receiver 810 demodulates the receive signal 912 to generate a baseband signal 914. Not accounting for transmission errors, the baseband signal 914 corresponds to the sensor module baseband signal **842** (FIG. **8**), for example a symbol stream of two bits each. The decoder 920 assembles the baseband signal 914 into a parameter signal 924, which, for example, may be a sequence of digital words corresponding to oxygen saturation and pulse rate. Again, not accounting for transmission errors, the monitor module parameter signal 924 corresponds to the sensor module parameter signal 832 (FIG. 8), derived by the signal processor 830 (FIG. 8).

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Also shown in FIG. 9, the waveform generator 930 is a particular embodiment of the waveform processor 730 (FIG. 7) described above. The waveform generator 930 generates a synthesized waveform 932 that the pulse oximeter monitor 360 can process to calculate SpO₂ and pulse rate values or 5 exception messages. In the present embodiment, the waveform generator output does not reflect a physiological waveform. In particular, the synthesized waveform is not physiological data from the sensor module 800, but is a waveform synthesized from predetermined stored waveform data to 10 cause the monitor 360 to calculate oxygen saturation and pulse rate equivalent to or generally equivalent (within clinical significance) to that calculated by the signal processor 830 (FIG. 8). The actual intensity signal from the patient received by the detector 314 (FIG. 8) is not provided to the 15 monitor 360 in the present embodiment. Indeed, the waveform provided to the monitor 360 will usually not resemble a plethysmographic waveform or other physiological data from the patient to whom the sensor module 800 (FIG. 8) is attached.

The synthesized waveform 932 is modulated according to the drive signal input 934. That is, the pulse oximeter monitor 360 expects to receive a red and IR modulated intensity signal originating from a detector, as described with respect to FIGS. 1-2, above. The waveform generator 25 930 generates the synthesized waveform 932 with a predetermined shape, such as a triangular or sawtooth waveform stored in waveform generator memory or derived by a waveform generator algorithm. The waveform is modulated synchronously with the drive input 934 with first and second 30 amplitudes that are processed in the monitor 360 as red and IR portions of a sensor signal. The frequency and the first and second amplitudes are adjusted so that pulse rate and oxygen saturation measurements derived by the pulse oximeter monitor 360 are generally equivalent to the parameter 35 measurements derived by the signal processor 830 (FIG. 8), as described above. One embodiment of a waveform generator 930 is described in U.S. Patent Application No. 60/117,097 entitled "Universal/Upgrading Pulse Oximeter," assigned to Masimo Corporation, Irvine, Calif. and incor- 40 porated by reference herein. Although the waveform generator 930 is described above as synthesizing a waveform that does not resemble a physiological signal, one of ordinary skill will recognize that another embodiment of the waveform generator 930 could incorporate, for example, a 45 plethysmograph simulator or other physiological signal simulator.

Further shown in FIG. 9, the interface cable 950 functions in a manner similar to the monitor interface 750 (FIG. 7) described above. The interface cable 950 is configured to 50 communicate the synthesized waveform 932 to the monitor 360 sensor port and to communicate the sensor drive signal 934 to the waveform generator 930. The interface cable 950 may include a ROM 960 that contains monitor and sensor characterization data. The ROM 960 is read by the wave- 55 form generator 930 so that the synthesized waveform 932 is adapted to a particular monitor 360. For example, the ROM 960 may contain calibration data of red/IR versus oxygen saturation, waveform amplitude and waveform shape information. An interface cable is described in U.S. Patent 60 Application No. 60/117,092, referenced above. Monitorspecific SatShareTM brand interface cables are available from Masimo Corporation, Irvine, Calif. In an alternative embodiment, such as a direct connect monitor module as illustrated in FIG. 5A, an interface cable 950 is not used and 65 the ROM 960 may be incorporated within the monitor module 900 itself.

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Plethysmograph Transmission

FIG. 10 illustrates another pulse oximetry sensor module 1000 having a sensor interface 1010, encoder 1040, transmitter 1050, transmitting antenna 1070 and controller 1090, which have the corresponding functions as those described with respect to FIG. 8, above. The encoder 1040, however, inputs a plethysmograph signal 1014 rather than oxygen saturation and pulse rate measurements 832 (FIG. 8). Thus, the sensor module 1000 according to this embodiment encodes and transmits a plethysmograph signal 1014 to a corresponding monitor module 1100 (FIG. 11) in contrast to derived physiological parameters, such as oxygen saturation and pulse rate. The plethysmograph signal 1014 is illustrated in FIG. 10 as being a direct output from the sensor interface 1010. In another embodiment, the sensor module 1000 incorporates a decimation processor, not shown, after the sensor interface 1010 so as to provide a plethysmograph signal 1014 having a reduced sample rate.

FIG. 11 illustrates another pulse oximetry monitor module 20 1100 having a receive antenna 1170, a receiver 1110, a decoder 1120 and an interface cable 1150, which have the corresponding functions as those described with respect to FIG. 9, above. This monitor module embodiment 1100, however, has a waveform modulator 1200 rather than a waveform generator 930 (FIG. 9), as described above. The waveform modulator 1200 inputs a plethysmograph signal from the decoder 1120 rather than oxygen saturation and pulse rate measurements, as described with respect to FIG. 9, above. Further, the waveform modulator 1200 provides an modulated waveform 1132 to the pulse oximeter monitor 360 rather than a synthesized waveform, as described with respect to FIG. 9. The modulated waveform 1132 is a plethysmographic waveform modulated according to the monitor drive signal input 1134. That is, the waveform modulator 1200 does not synthesize a waveform, but rather modifies the received plethysmograph signal 1124 to cause the monitor 360 to calculate oxygen saturation and pulse rate generally equivalent (within clinical significance) to that derivable by a compatible, calibrated pulse oximeter directly from the sensor signal 1012 (FIG. 10). The waveform modulator 1200 is described in further detail with respect to FIG. 12, below.

FIG. 12 shows a waveform modulator 1200 having a demodulator 1210, a red digital-to-analog converter (DAC) 1220, an IR DAC 1230, a red amplifier 1240, an IR amplifier 1250, a modulator 1260, a modulator control 1270, a look-up table (LUT) 1280 and a ratio calculator 1290. The waveform modulator 1200 demodulates red and IR plethysmographs ("pleths") from the decoder output 1124 into a separate red pleth 1222 and IR pleth 1232. The waveform modulator 1200 also adjusts the amplitudes of the pleths 1222, 1232 according to stored calibration curves for the sensor 310 (FIG. 10) and the monitor 360 (FIG. 11). Further, the waveform modulator 1200 re-modulates the adjusted red pleth 1242 and adjusted IR pleth 1252, generating a modulated waveform 1132 to the monitor 360 (FIG. 11).

As shown in FIG. 12, the demodulator 1210 performs the demodulation function described above, generating digital red and IR pleth signals 1212, 1214. The DACs 1220, 1230 convert the digital pleth signals 1212, 1214 to corresponding analog pleth signals 1222, 1232. The amplifiers 1240, 1250 have variable gain control inputs 1262, 1264 and perform the amplitude adjustment function described above, generating adjusted red and IR pleth signals 1242, 1252. The modulator 1260 performs the re-modulation function described above, combining the adjusted red and IR pleth signals 1242, 1252 according to a control signal 1272. The

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modulator control 1270 generates the control signal 1272 synchronously with the LED drive signal(s) 1134 from the monitor 360

Also shown in FIG. 12, the ratio calculator 1290 derives a red/IR ratio from the demodulator outputs 1212, 1214. The 5 LUT 1280 stores empirical calibration data for the sensor 310 (FIG. 10). The LUT 1280 also downloads monitor-specific calibration data from the ROM 1160 (FIG. 11) via the ROM output 1158. From this calibration data, the LUT 1280 determines a desired red/IR ratio for the modulated 10 waveform 1132 and generates red and IR gain outputs 1262, 1264 to the corresponding amplifiers 1240, 1250, accordingly. A desired red/IR ratio is one that allows the monitor 360 (FIG. 11) to derive oxygen saturation measurements from the modulated waveform 1132 that are generally 15 equivalent to that derivable directly from the sensor signal 1012 (FIG. 10).

One of ordinary skill in the art will recognize that some of the signal processing functions described with respect to FIGS. **8-11** may be performed either within a sensor module 20 or within a monitor module. Signal processing functions performed within a sensor module may advantageously reduce the transmission bandwidth to a monitor module at a cost of increased sensor module size and power consumption. Likewise, signal processing functions performed 25 within a monitor module may reduce sensor module size and power consumption at a cost of increase transmission bandwidth.

For example, a monitor module embodiment 900 (FIG. 9) described above receives measured pulse oximeter param- 30 eters, such as oxygen saturation and pulse rate, and generates a corresponding synthesized waveform. In that embodiment, the oxygen saturation and pulse rate computations are performed within a sensor module 800 (FIG. 8). Another monitor module embodiment 1100 (FIG. 11), also described 35 above, receives a plethysmograph waveform and generates a remodulated waveform. In that embodiment, minimal signal processing is performed within a sensor module 1000 (FIG. 10). In yet another embodiment, not shown, a sensor module transmits a plethysmograph waveform or a deci- 40 mated plethysmograph waveform having a reduced sample rate. A corresponding monitor module has a signal processor, such as described with respect to FIG. 8, in addition to a waveform generator, as described with respect to FIG. 9. The signal processor computes pulse oximeter parameters 45 and the waveform generator generates a corresponding synthesized waveform, as described above. In this embodiment, minimal signal processing is performed within the sensor module, and the monitor module functions are performed on the pulse oximeter parameters computed within 50 the monitor module.

Wireless Multiple Parameter Measurements

FIGS. 13-14 illustrate a multiple parameter communications adapter. FIG. 13 illustrates a multiple parameter sensor module 1300 having sensor interfaces 1310, one or more 55 signal processors 1330, a multiplexer and encoder 1340, a transmitter 1350, a transmitting antenna 1370 and a controller 1390. One or more physiological sensors 1301 provide input sensor signals 1312 to the sensor module 1300. Depending on the particular sensors 1301, the sensor module 1300 may provide one or more drive signals 1312 to the sensors 1301 as determined by the controller 1390. The sensor interfaces 1310 input the sensor signals 1312 and output one or more conditioned signals 1314. The conditioned signals 1314 may be coupled to the transmitter 1350 or further processed by the signal processors 1330. If the sensor module configuration utilizes signal processors 1330,

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it derives multiple parameter signals 1332 responsive to the sensor signals 1312, which are then coupled to the transmitter 1350. Regardless, the transmitter 1350 inputs a baseband signal 1342 that is responsive to the sensor signals 1312. The transmitter 1350 modulates the baseband signal 1342 with a carrier to generate a transmit signal 1354, which is coupled to the transmit antenna 1370 and communicated to a corresponding receive antenna 1470 (FIG. 14), as described with respect to FIG. 6, above. Alternatively, there may be multiple baseband signals 1342, and the transmitter 1350 may transmit on multiple frequency channels, where each channel coveys data responsive to one or more of the sensor signals 1314.

As shown in FIG. 13, the sensor interface 1310 conditions and digitizes the sensor signals 1312 as described for a single sensor with respect to FIG. 6, above. The resulting conditioned signals 1314 are responsive to the sensor signals 1312. The signal processors 1330 perform signal processing on the conditioned signals 1314 to derive parameter signals 1332, as described for a single conditioned signal with respect to FIG. 6, above. The parameter signals 1332 may be physiological measurements such as oxygen saturation, pulse rate, blood glucose, blood pressure, EKG, respiration rate and body temperature to name a few, or may be intermediate results from which the above-stated measurements may be calculated or derived. The multiplexer and encoder 1340 combines multiple digital word or serial bit streams into a single digital word or bit stream. The multiplexer and encoder also encodes the digital word or bit stream to generate the baseband signal 1342, as described with respect to FIG. 6, above.

FIG. 14 illustrates a multiple parameter monitor module 1400 having a receive antenna 1470, a receiver 1410, a demultiplexer and decoder 1420, one or more waveform processors 1430 and a monitor interface 1450. The receiver 1410 inputs and demodulates the receive signal 1412 corresponding to the transmit signal 1354 (FIG. 13) to generate a baseband signal 1414 as described with respect to FIG. 7, above. The demultiplexer and decoder 1420 separates the symbol streams corresponding to the multiple conditioned signals 1314 (FIG. 13) and/or parameter signals 1332 (FIG. 13) and translates these symbol streams into multiple decoded signals 1422, as described for a single symbol stream with respect to FIG. 7, above. Alternatively, multiple frequency channels are received to generate multiple baseband signals, each of which are decoded to yield multiple decoded signals 1422. The waveform processors 1430 input the decoded signals 1422 and generate multiple constructed signals 1432, as described for a single decoded signal with respect to FIGS. 7-12, above. The monitor interface 1450 is configured to communicate the constructed signals 1432 to the sensor ports of a multiple parameter monitor 1401 or multiple single parameter monitors, in a manner similar to that for a single constructed signal, as described with respect to FIGS. 7-12, above. In particular, the constructed signals 1432 are adapted to the monitor 1401 so that measurements derived by the monitor 1401 from the constructed signals 1432 are generally equivalent to measurements derivable directly from the sensor signals 1312 (FIG. 13).

A physiological measurement communications adapter is described above with respect to wireless communications and, in particular, radio frequency communications. A sensor module and monitor module, however, may also communicate via wired communications, such as telephone, Internet or fiberoptic cable to name a few. Further, wireless communications can also utilize light frequencies, such as IR or laser to name a few.

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A physiological measurement communications adapter has been disclosed in detail in connection with various embodiments. These embodiments are disclosed by way of examples only. One of ordinary skill in the art will appreciate many variations and modifications of a physiological 5 measurement communications adapter within the scope of the claims that follow.

What is claimed is:

- 1. An arm mountable portable patient monitoring device 10 configured to receive physiological information from a plurality of sensors attached to a patient at at least two different measurement sites via wired connections for onpatient monitoring of parameter measurements and wireless transmission of parameter measurements to separate moni- 15 further comprising: toring devices, the portable patient monitoring device com
 - a housing configured to be secured to an arm of a patient under measurement;
 - a strap mountable to a back side of the housing and 20 configured to secure the housing to the arm of the
 - a display positioned on a front side of the housing, the display configured to show at least one status indicator of the portable patient monitoring device and one or 25 more parameter measurements;
 - a first sensor port positioned on a first side of the housing, the first side of the housing configured to face toward a hand of the arm of the patient when the housing is secured to the arm of the patient, the first sensor port 30 configured to electrically receive a signal from a pulse oximetry sensor via a wired connection from the pulse oximetry sensor to the first sensor port, the wired connection configured to extend from the first sensor port along a path substantially perpendicular to the first 35 side of the housing;
 - a second sensor port positioned on the housing and configured to receive a signal from a second sensor arrangement via a wired connection;
 - receive a signal from a third sensor arrangement via a wired connection;
 - one or more signal processing arrangements configured
 - receive the signal from the pulse oximetry sensor; and 45 cause to be displayed, on the display, at least measurements of oxygen saturation and pulse rate derived from the signal; and
 - a transmitter configured to:
 - wirelessly transmit information indicative of the mea- 50 surements of oxygen saturation and pulse rate to a separate monitoring device configured to receive the information indicative of the measurements of oxygen saturation and pulse rate.
- 2. The portable patient monitoring device of claim 1, 55 wherein the wired connection from the pulse oximetry sensor to the first sensor port is provided at least in part via a tail of the pulse oximetry sensor.
- 3. The portable patient monitoring device of claim 2, wherein the wired connection is configured to run from the 60 first sensor port, at least part way down the arm of the patient, and to a digit of the patient to which the pulse oximetry sensor is configured to be attached.
- 4. The portable patient monitoring device of claim 3, wherein the digit is a thumb of the patient.
- 5. The portable patient monitoring device of claim 1 further comprising:

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- a cable providing the wired connection from the pulse oximetry sensor to the first sensor port.
- 6. The portable patient monitoring device of claim 5, wherein the cable is configured to be removably coupled to the housing via the first sensor port.
- 7. The portable patient monitoring device of claim 6, wherein the cable is configured to run from the first sensor port, at least part way down the arm of the patient, and to a digit of the patient to which the pulse oximetry sensor is configured to be attached, wherein the digit is on the hand of the arm of the patient.
- 8. The portable patient monitoring device of claim 7, wherein the digit is a thumb of the patient.
- **9**. The portable patient monitoring device of claim **1**,
- a battery configured to provide power to at least the display and the first sensor port.
- 10. The portable patient monitoring device of claim 1, wherein the front side of the housing comprises a single user interface.
- 11. The portable patient monitoring device of claim 10, wherein the single user interface comprises the display.
- 12. The portable patient monitoring device of claim 11, wherein the display is positioned centrally on the front side of the housing.
- 13. The portable patient monitoring device of claim 12, wherein the display positioned on the front side of the housing is sized such that the display covers most of a length of a shortest dimension of the front side of the housing.
- 14. The portable patient monitoring device of claim 1, wherein the one or more signal processing arrangements are further configured to:
 - receive signals from the second and third sensor arrangements; and
 - cause to be displayed, on the display, at least measurements of one or more additional physiological parameters based on the signals from the second and third sensor arrangements.
- 15. The portable patient monitoring device of claim 14, a third sensor port positioned on the housing configured to 40 wherein the one or more signal processing arrangements are further configured to:
 - receive signals from the second and third sensor arrangements; and
 - cause to be displayed, on the display, measurements of all of the oxygen saturation, pulse rate, and the one or more additional physiological parameters.
 - 16. The portable patient monitoring device of claim 15, wherein the transmitter is further configured to:
 - wirelessly transmit information indicative of the measurements of oxygen saturation, pulse rate, and the one or more additional physiological parameters to the separate monitoring device.
 - 17. A method of portable patient monitoring comprising: providing a portable patient monitoring device according to claim 1;
 - attaching the strap to the arm of the patient;
 - mounting the housing to the strap such that the first sensor port positioned on a first side of the housing faces toward the hand of the arm of the patient;
 - wrapping the pulse oximetry sensor around a digit of the hand of the patient;
 - attaching the wired connection from the pulse oximetry sensor to the first sensor port positioned on the first side of the housing; and
 - activating the portable patient monitoring device such that measurements of oxygen saturation and pulse rate are

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displayed on the display of the portable patient monitoring device on the patient; and

wirelessly transmitted to the separate monitoring device configured to receive the measurements of oxygen saturation and pulse rate.

18. The method of claim 17, further comprising:

attaching the second sensor arrangement to a second measurement site on the patient different from the hand of the patient;

- attaching the wired connection from the second sensor 10 arrangement to the second sensor port;
- attaching the third sensor arrangement to a third measurement site on the patient different from both the hand of the patient and the second measurement site; and
- attaching the wired connection from the third sensor 15 arrangement to the third sensor port,
- wherein the portable patient monitoring device is further activated such that measurements of one or more additional physiological parameters are both:
 - displayed on the display of the portable patient monitoring device on the patient; and
 - wirelessly transmitted to the separate monitoring device.
- 19. An arm mountable portable patient monitoring device configured to receive physiological information from a plurality of sensors attached to a patient at at least two different measurement sites via wired connections for onpatient monitoring of parameter measurements and wireless transmission of parameter measurements to separate monitoring devices, the portable patient monitoring device comprising:
 - a housing configured to be secured to an arm of a patient under measurement, the housing comprising a front side including a single user interface, the single user interface comprising a display configured to show at least one or more parameter measurements;
 - a strap mountable to a back side of the housing and configured to secure the housing to the arm of the patient;
 - a first sensor port positioned on a first side of the housing, the first side of the housing configured to face toward a hand of the arm of the patient when the housing is secured to the arm of the patient, the first sensor port configured to electrically receive a signal from a pulse oximetry sensor via a wired connection from the pulse oximetry sensor to the first sensor port, the signal from the pulse oximetry sensor including analog information;
 - a second sensor port positioned on the housing and configured to receive a signal from a second sensor arrangement via a wired connection, the signal from the second sensor arrangement including digital information;
 - a third sensor port positioned on the housing configured to receive a signal from a third sensor arrangement via a wired connection;

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one or more signal processing arrangements configured to:

receive the signal from the pulse oximetry sensor including the analog information;

receive the signal from the second sensor arrangement including the digital information;

determine digital transmit information based at least in part on: the analog information included in the signal from the pulse oximetry sensor, and the digital information included in the signal from the second sensor arrangement; and

cause to be displayed, on the display, at least measurements of oxygen saturation and pulse rate derived from the signal from the pulse oximetry sensor; and

a transmitter configured to:

- wirelessly transmit the digital transmit information to a separate monitoring device configured to receive the digital transmit information, wherein the digital transmit information includes at least measurements of oxygen saturation and pulse rate derived from the signal from the pulse oximetry sensor, and wherein the digital transmit information further includes at least physiological measurements derived from the signal from the second sensor arrangement.
- 20. The portable patient monitoring device of claim 19, wherein the display is positioned centrally on the front side of the housing and sized such that, if measured along a shortest dimension of the front side of the housing, the display comprises most of a length of the shortest dimension
 - 21. A method of portable patient monitoring comprising: providing a portable patient monitoring device according to claim 19:
 - attaching the housing to the arm of the patient via the strap such that the first sensor port positioned on a first side of the housing faces toward the hand of the arm of the patient;
 - attaching the pulse oximetry sensor to a digit of the hand of the patient;
 - attaching the second sensor arrangement to the patient; attaching the wired connection from the pulse oximetry sensor to the first sensor port positioned on the first side of the housing;
 - attaching the wired connection from the second sensor arrangement to the second sensor port; and
 - activating the portable patient monitoring device such that measurements of oxygen saturation and pulse rate are displayed on the display of the portable patient monitoring device on the patient.
- 22. The method of claim 21, wherein activating the portable patient monitoring device further includes causing the digital transmit information to be wirelessly transmitted to the separate monitoring device configured to receive the digital transmit information.

* * * * *

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(12) United States Patent Sampath et al.

(54) PHYSIOLOGICAL PARAMETER ALARM

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DELAY

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(57) ABSTRACT

A system configured to reduce a frequency of alarms from a physiological monitoring system including a physiological sensor configured to detect signals representative of a physiological condition of a patient and a processor configured to receive the detected signals, determine a physiological parameter of the patient, detect an alarm condition and delay a notification of the alarm condition until a predetermined alarm delay period has elapsed.

8 Claims, 56 Drawing Sheets



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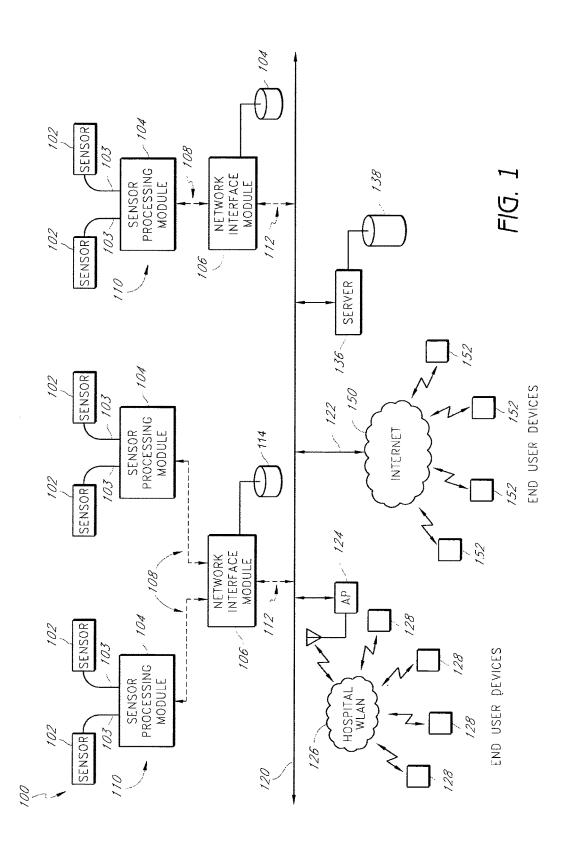
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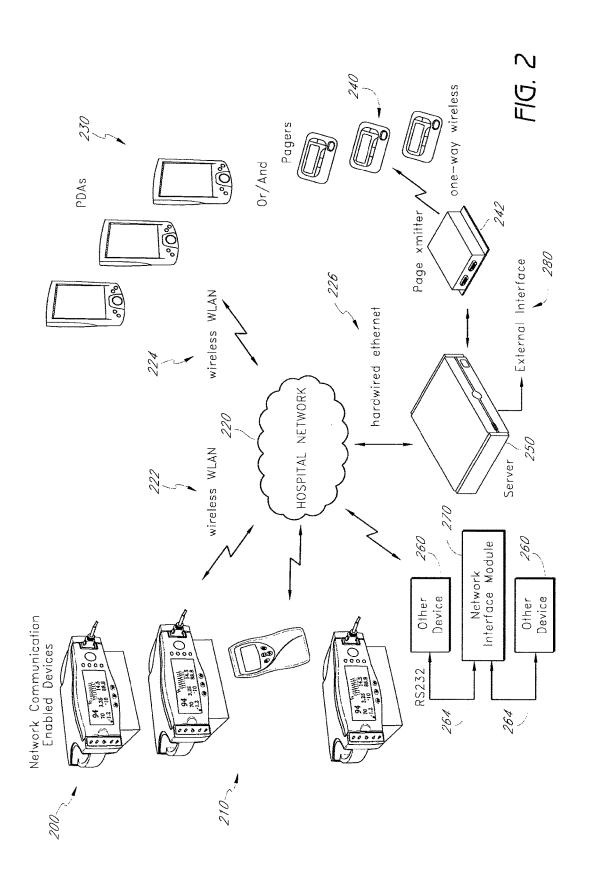
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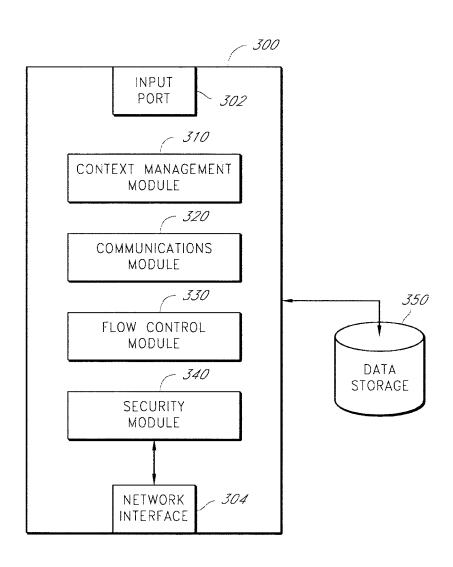
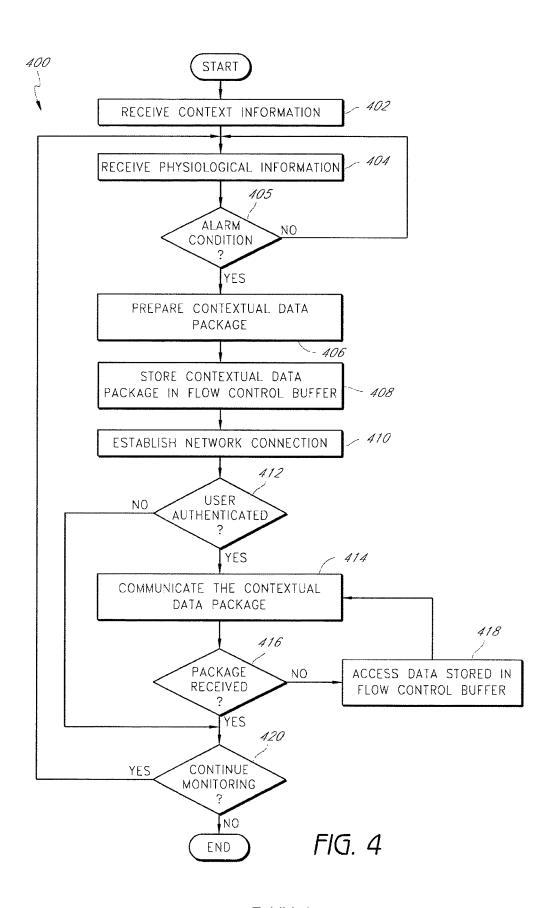


FIG. 3

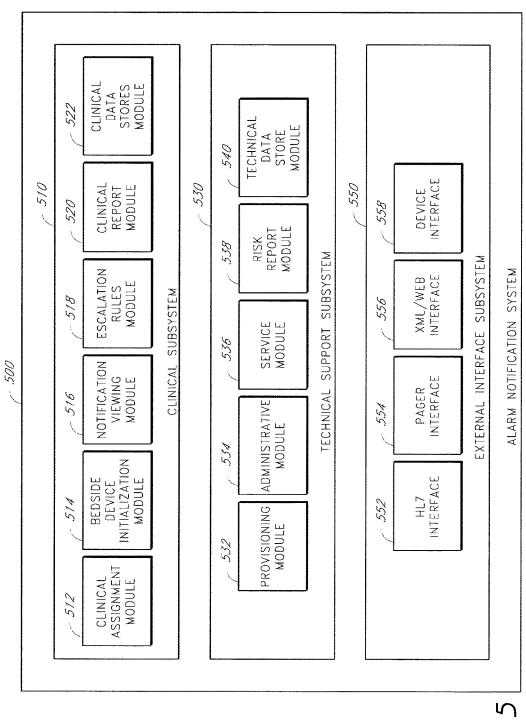
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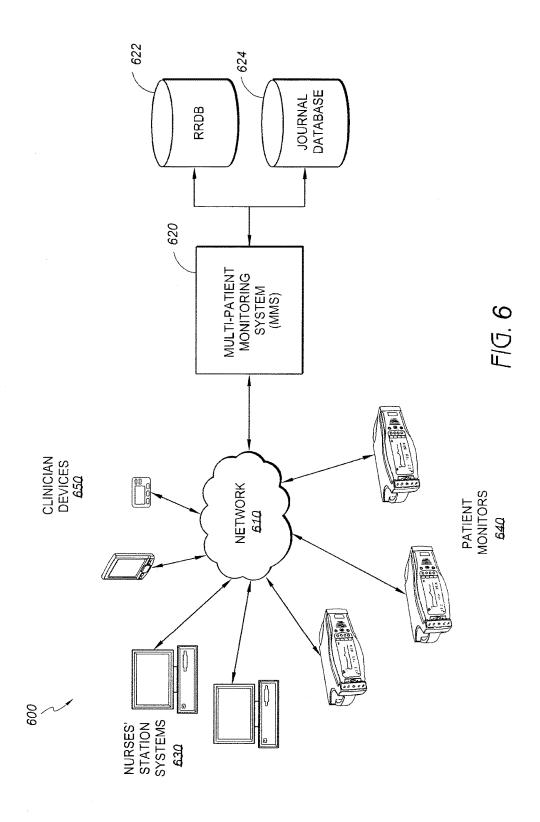
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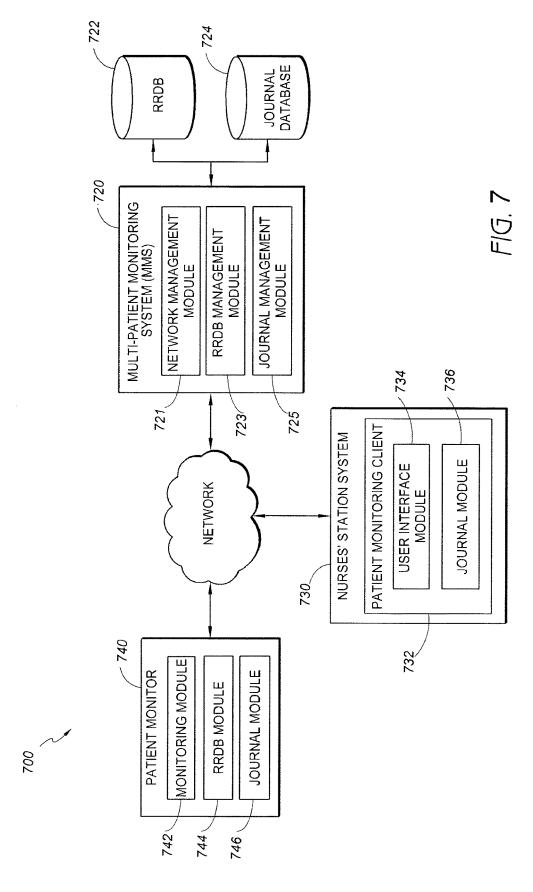


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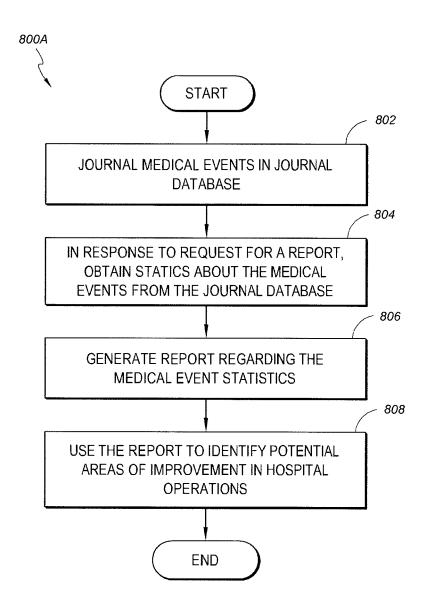


FIG.8A

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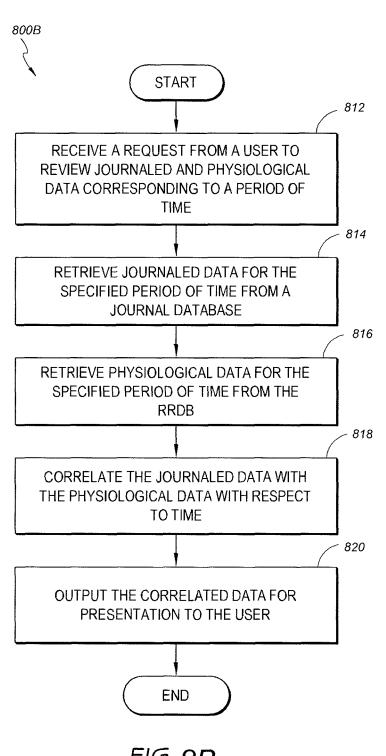
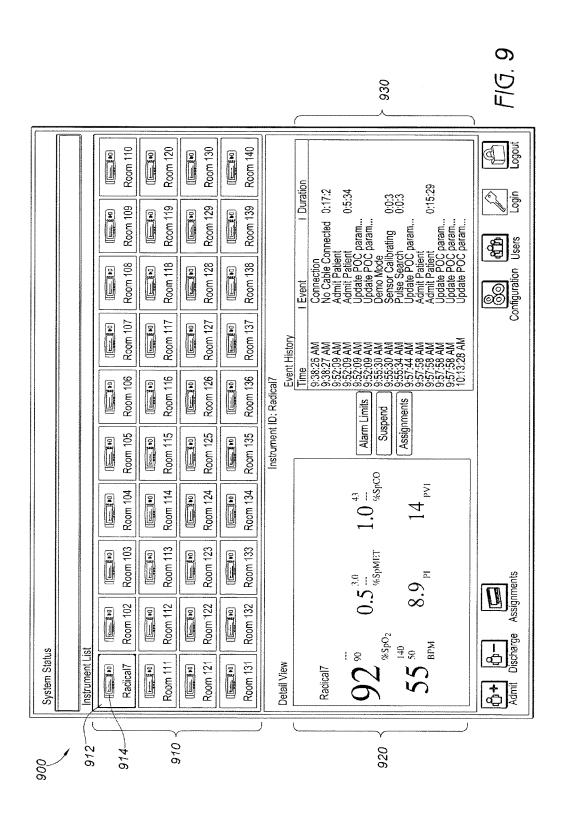


FIG.8B

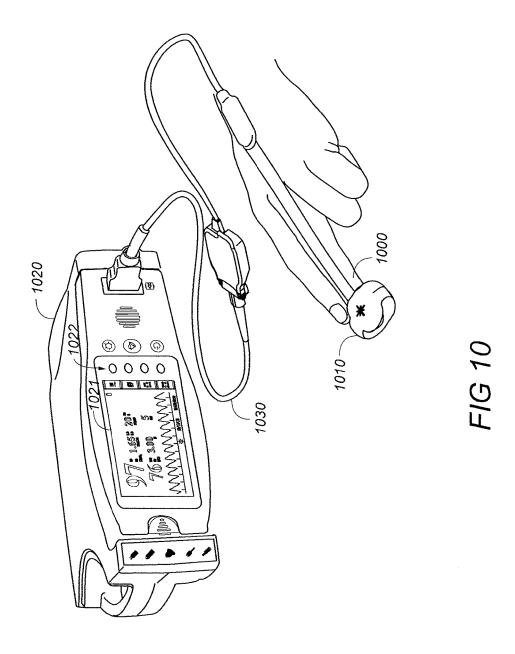
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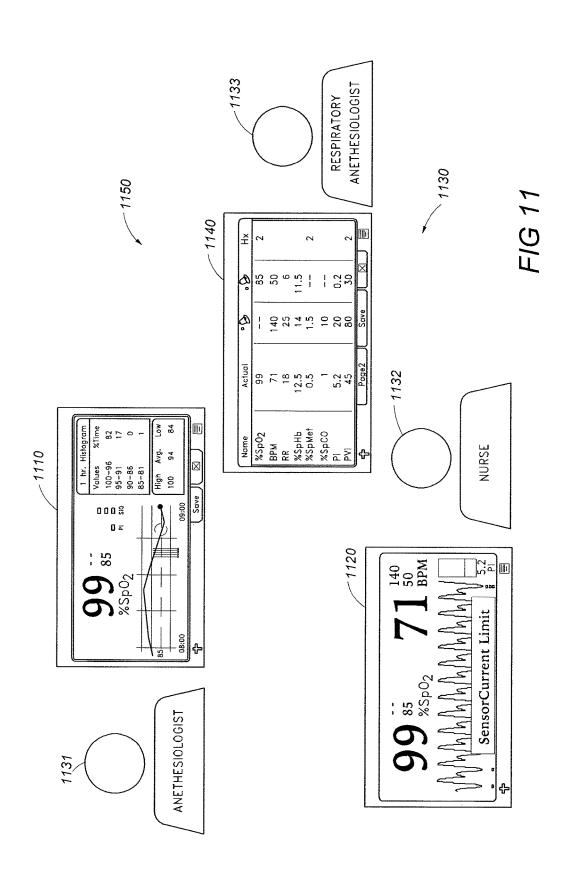
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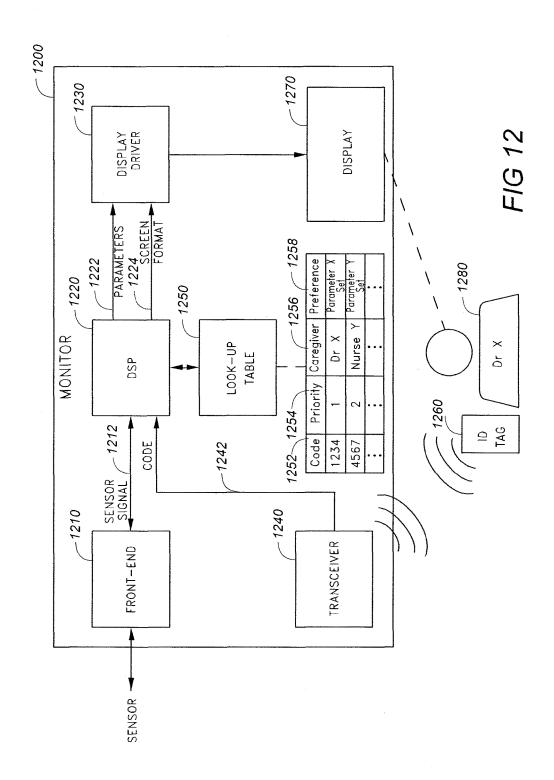
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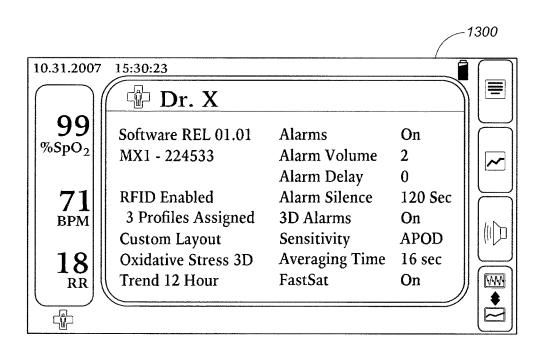


FIG 13

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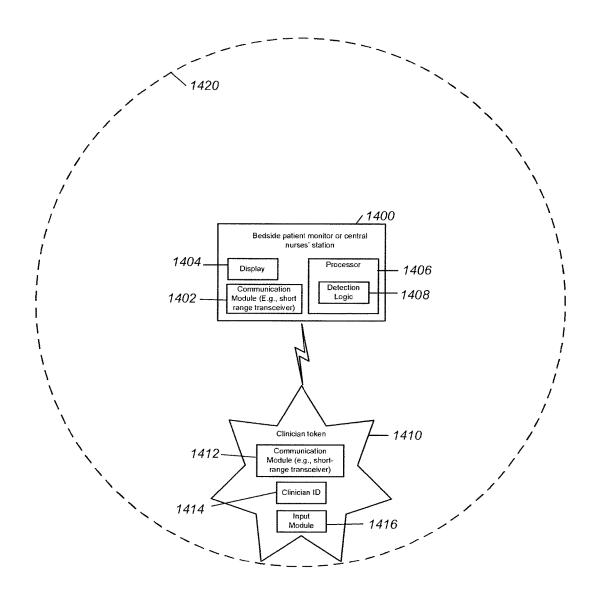


FIG 14

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<u>1500</u>

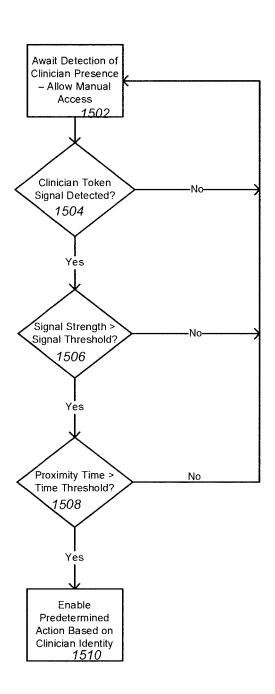


FIG 15

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1600

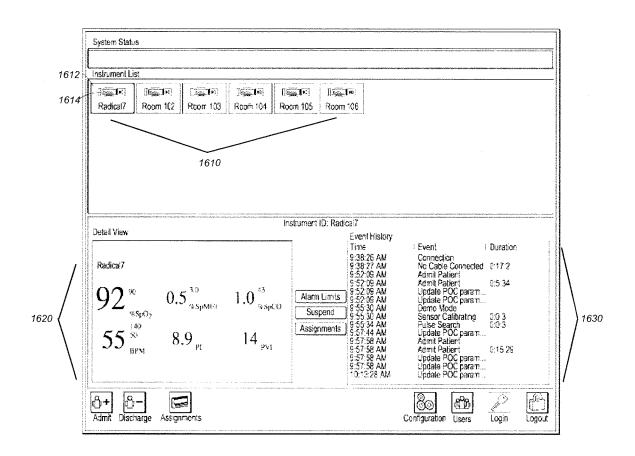


FIG 16

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<u>1700</u>

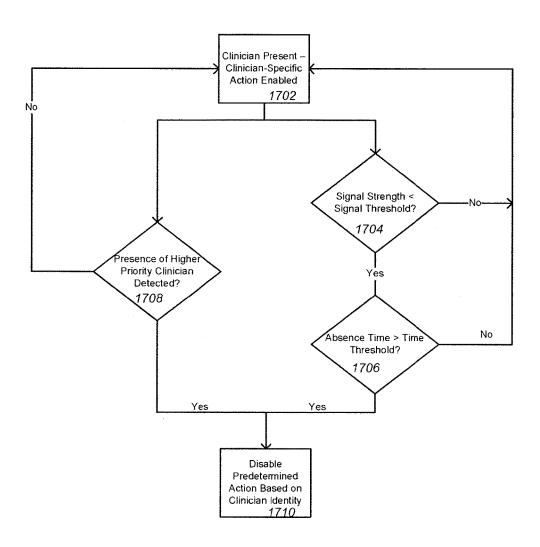


FIG 17

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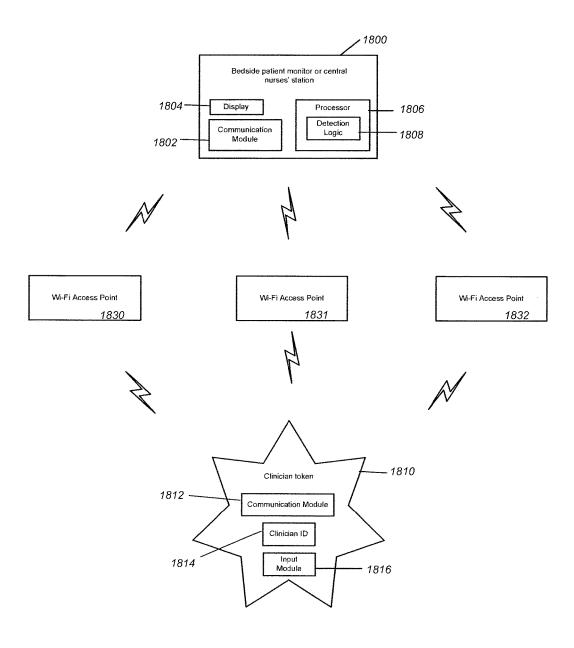


FIG 18

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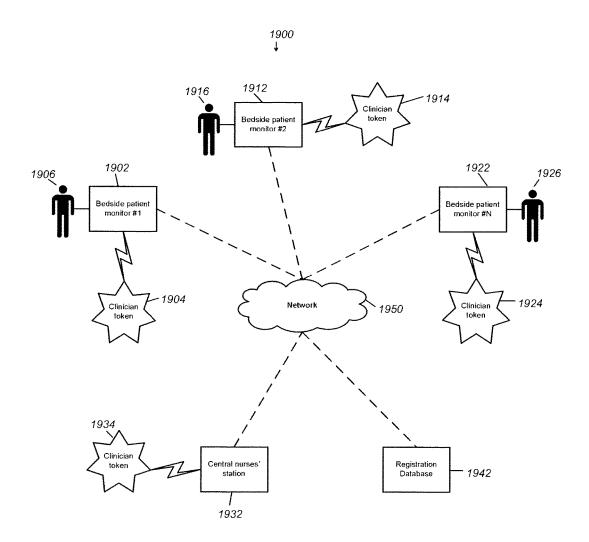
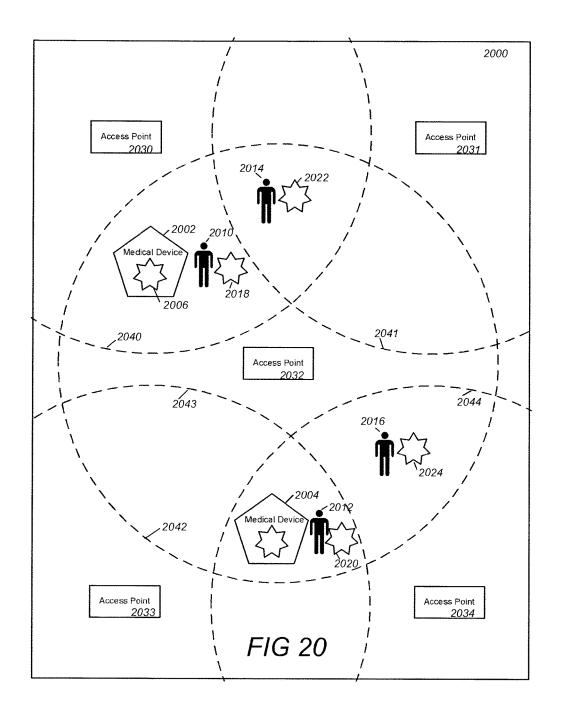


FIG 19

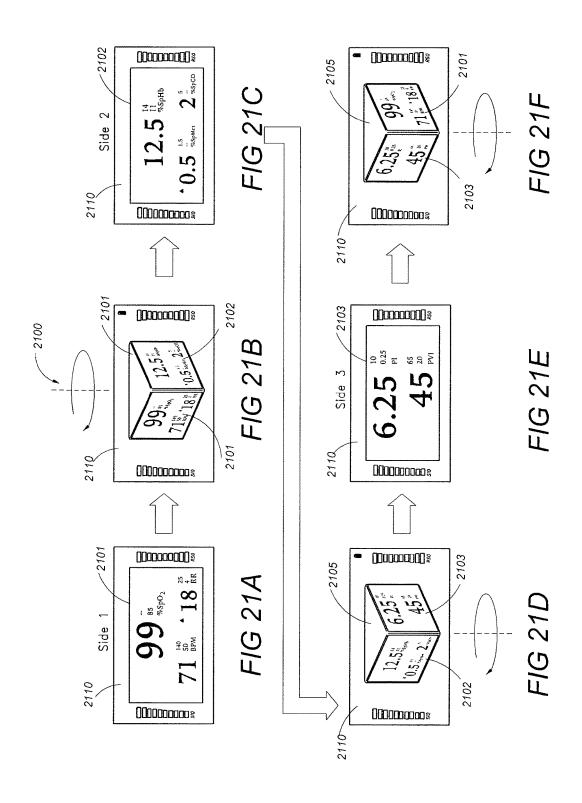
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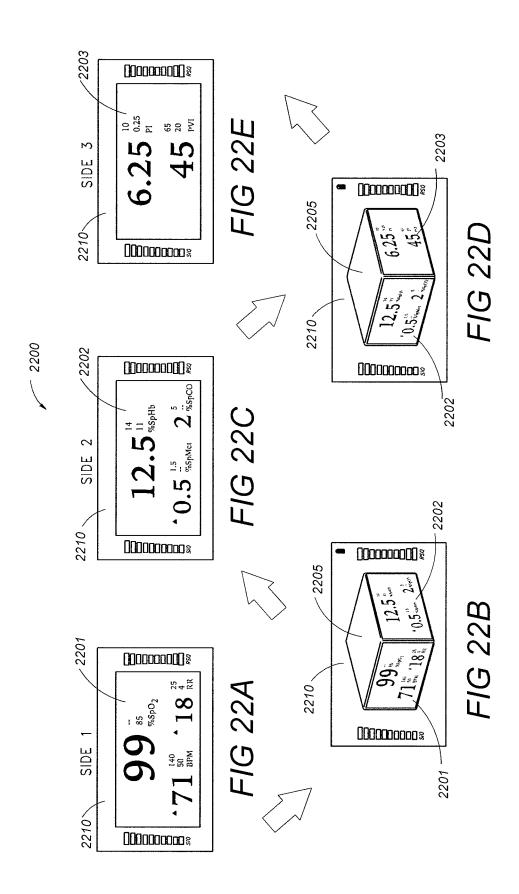


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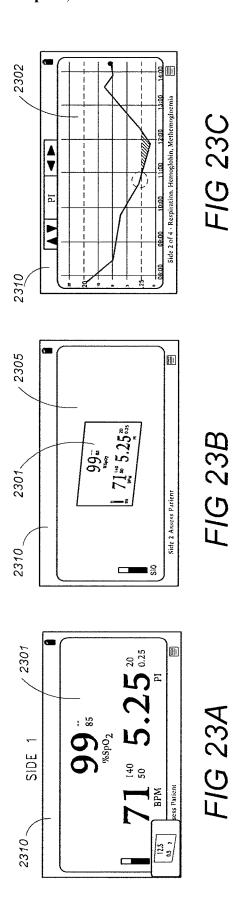


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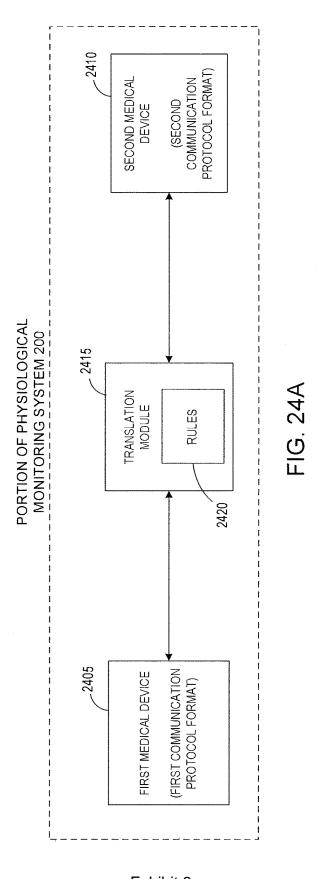


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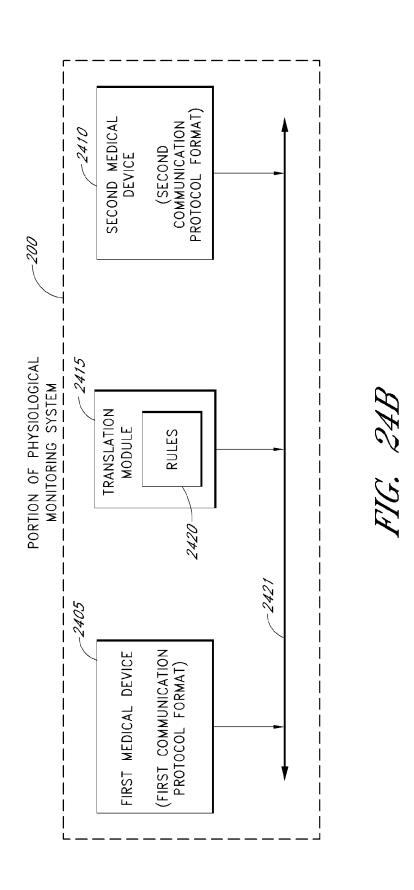
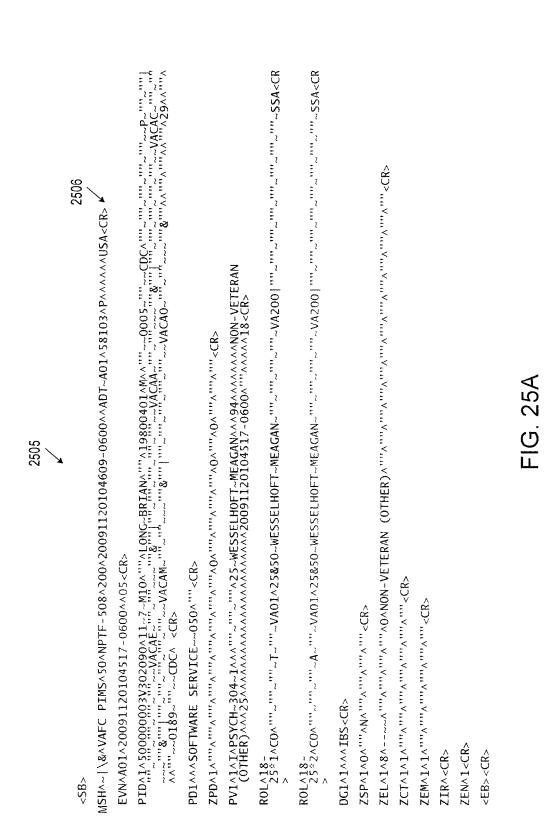


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```
<?xml version="1.0" encoding="UTF-8" standalone="no" ?>
  <ev7>
    <MSH>
      <MSH.1>^</MSH.1>
      <MSH. 2>~ \ &amp; </MSH. 2>
      <MSH.3>VAFC PIMS</MSH.3>
      <MSH.4>50</MSH.4>
      <MSH.5>NPTF-508</MSH.5>
      <MSH.6>200</MSH.6>
      <MSH.7>20091120104609-0600</mSH.7>
      <MSH.9>
        <component n="1">ADT</component>
        <component n="2">A01</component>
      </MSH.9>
      <MSH.10>58103</MSH.10>
      <MSH.11>P</MSH.11>
      <MSH.17>USA</MSH.17>
    </MSH>
    <EVN>
      <EVN.1>A01</EVN.1>
      <EVN.2>20091120104517-0600</EVN.2>
      <EVN.4>05</EVN.4>
    </EVN>
  <ev7>
```

FIG. 25B

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```
<?xml version="1.0" encoding="UTF-8"?>
<ADT_A01>
  <MSH>
    <MSH.1> \land </MSH.1>
    <MSH.2>\sim |\&amp;</MSH.2>
    <MSH.3>
      <HD.1>VAFC PIMS</HD.1>
    </MSH.3>
    <MSH.4>
      < HD.1 > 50 < / HD.1 >
    </MSH.4>
    <MSH.5>
      <HD.1>NPTF-508</HD.1>
    </MSH.5>
    <MSH.6>
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    </MSH.6>
    <MSH.7>
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    </MSH.7>
    <MSH.9>
      <MSG. 1>ADT</MSG. 1>
      <MSG.2>A01</MSG.2>
    </MSH.9>
    <MSH.10>58103</MSH.10>
    <MSH. 11>
      <PT. 1>P</PT. 1>
    </MSH.11>
    <MSH.17>USA</MSH.17>
  </MSH>
```

FIG. 25C

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```
2510
<output-message>
  <ACK>
    <MSH>
      <MSH. 1>\wedge</MSH. 1>
      <MSH.2>~|\&amp;</MSH.2>
      <MSH.3>
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      </MSH.3>
      <MSH.4>
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      </MSH.4>
      <MSH.5>
         <HD.1>VAFC PIMS</HD.1>
      </MSH.5>
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      </MSH.6>
      <MSH.7>
         <TS.1>20091120104619.8053-0800</TS.1>
      </MSH.7>
      <MSH.9>
         <MSG. 1>ACK</MSG. 1>
        <MSG. 3>ACK</MSG. 3>
      </MSH.9>
      <MSH.10>856bc9bd-97c8-4aa5-b411-3cd6fe2edd86
/MSH.10>...
    </MSH>
    <MSA>
      <MSA.1>AA</MSA.1>
      <MSA.2>58103</MSA.2>
    </MSA>
  </ACK>
</output-message>
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FIG. 25D

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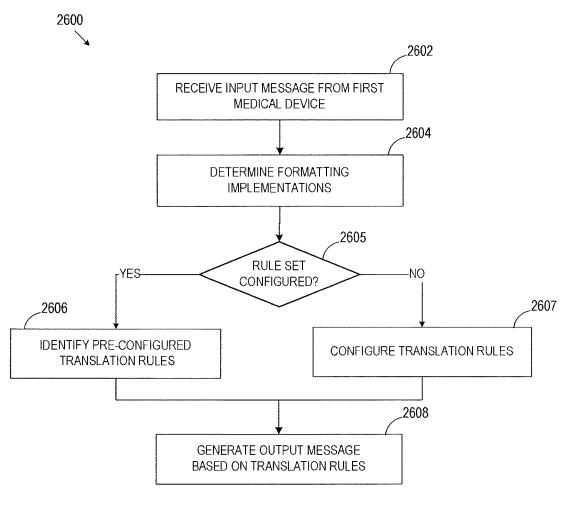
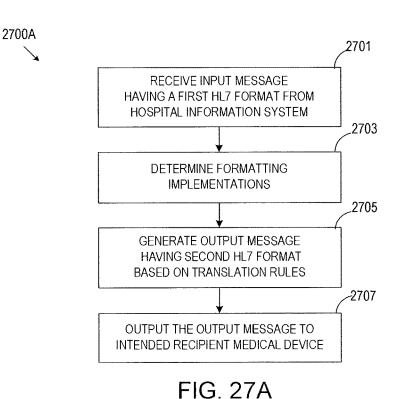


FIG. 26

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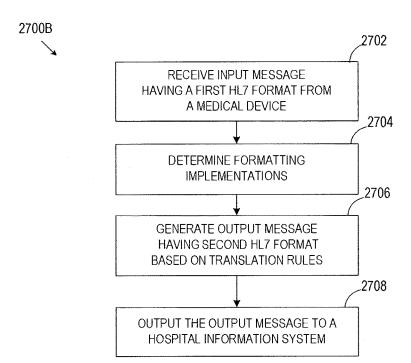


FIG. 27B

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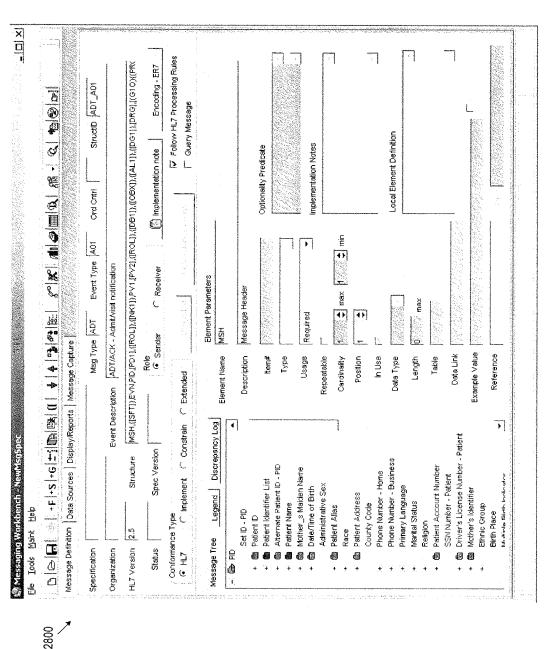


FIG. 28

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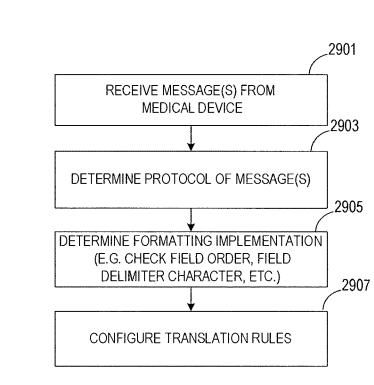


FIG. 29A

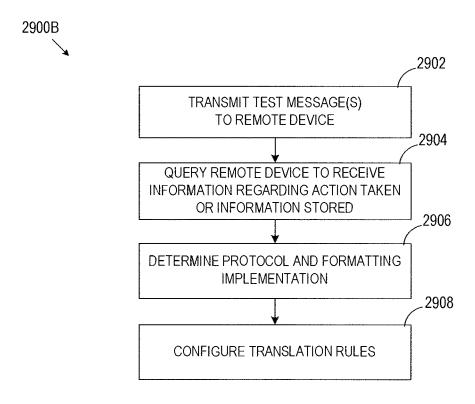


FIG. 29B

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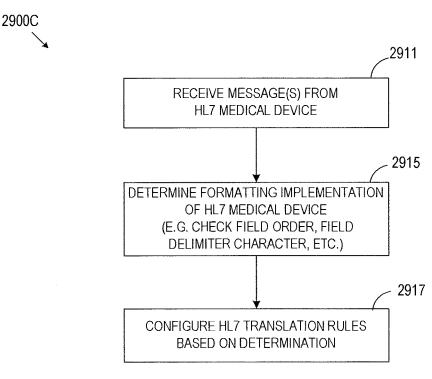


FIG. 29C

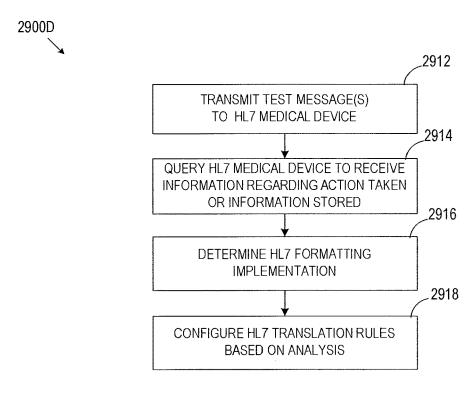


FIG. 29D

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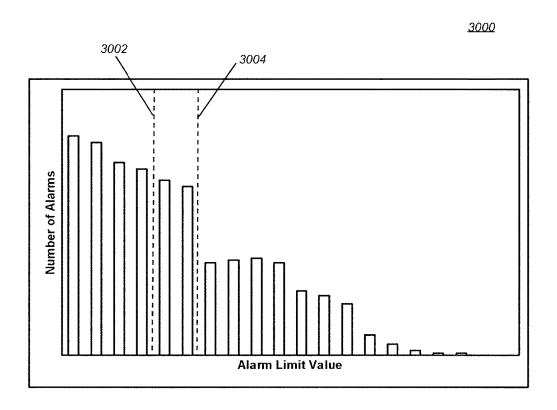


FIG 30

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<u>3100</u>

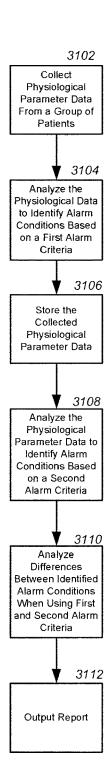


FIG 31

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3200

	Number of Alarms	Change Versus Actual Alarm Criteria		
	Alaillis	Afarm Chteria		
Simulated Alarm				
Criteria #1				
Simulated Alarm				
Criteria #2				
Simulated Alarm				
Criteria #3				
Simulated Alarm				
Criteria #4				
Simulated Alarm		<u></u>		
Criteria #5				

FIG 32

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3300

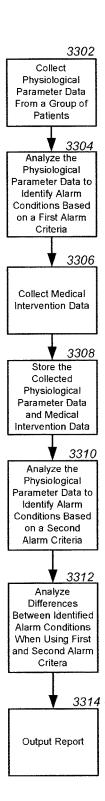


FIG 33

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3400 **/**

	Number of Alarms	Change Versus Actual Alarm Setting	Estimated False Negatives Detected	Estimated Accurate Alarms Undetected	
Simulated Alarm Criteria #1					
Simulated Alarm Criteria #2					
Simulated Alarm Criteria #3					
Simulated Alarm Criteria #4				***	
Simulated Alarm Criteria #5	· <u>-</u>			sian yea	

FIG 34

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<u>3500</u>

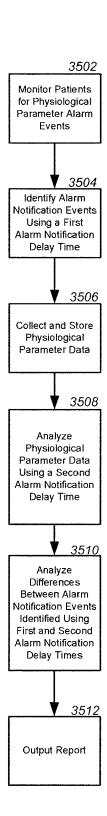


FIG 35

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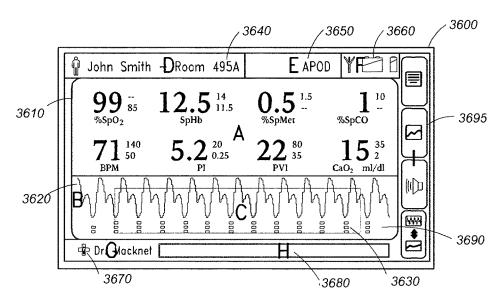


FIG 36A

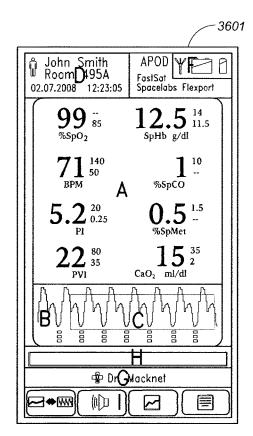
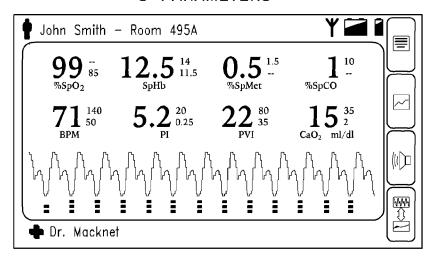


FIG 36B

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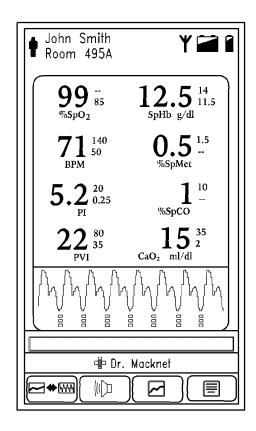
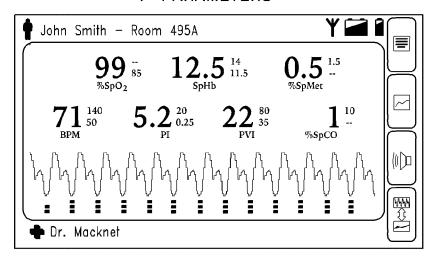


FIG. 37A

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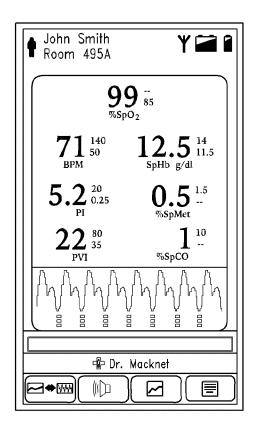
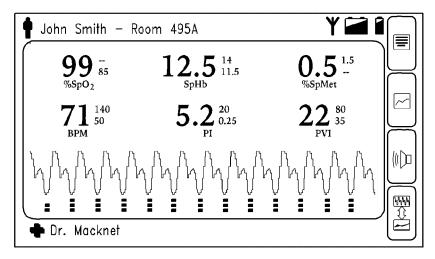


FIG. 37B

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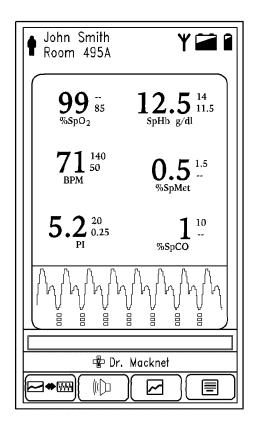
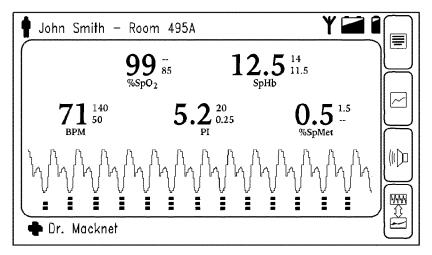


FIG. 37C

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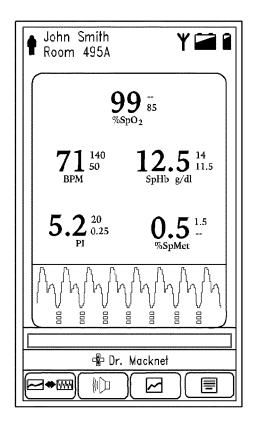
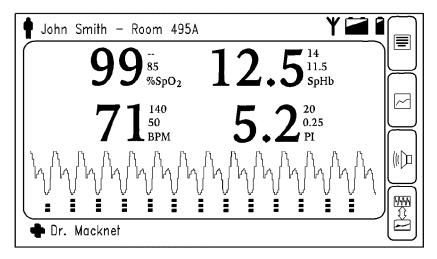


FIG. 37D

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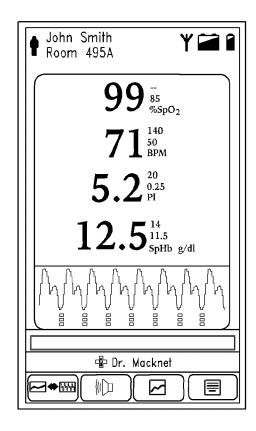


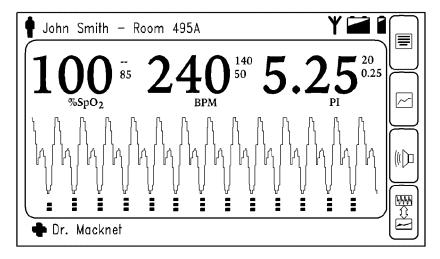
FIG. 37E

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3 PARAMETERS



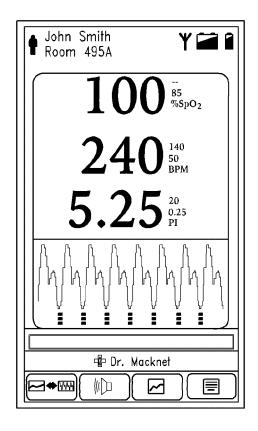


FIG. 37F

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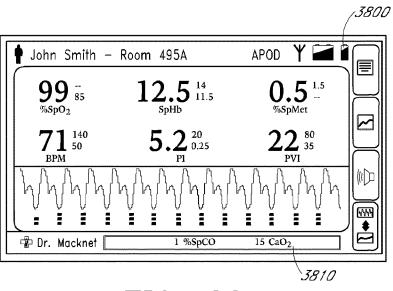


FIG. 38A

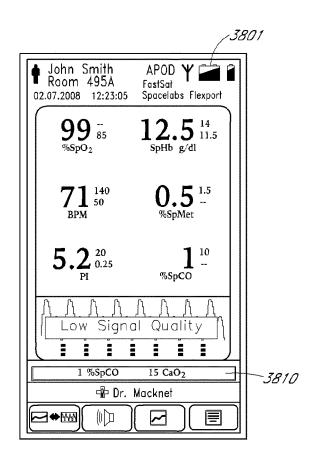


FIG. 38B

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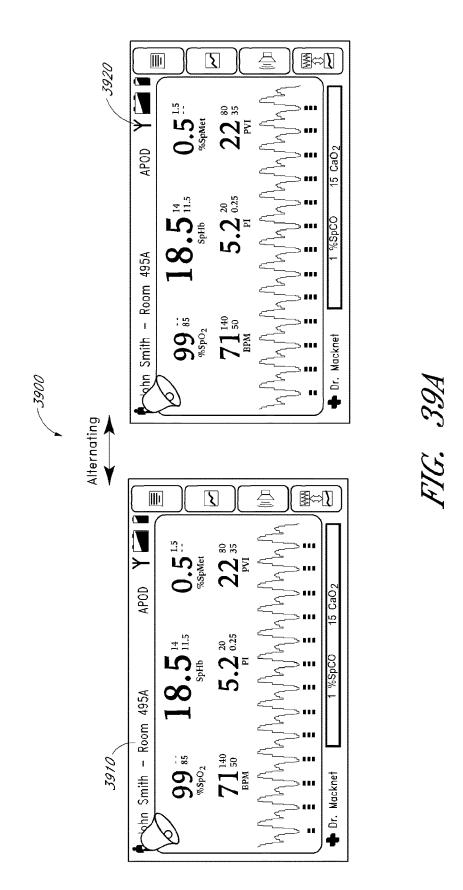


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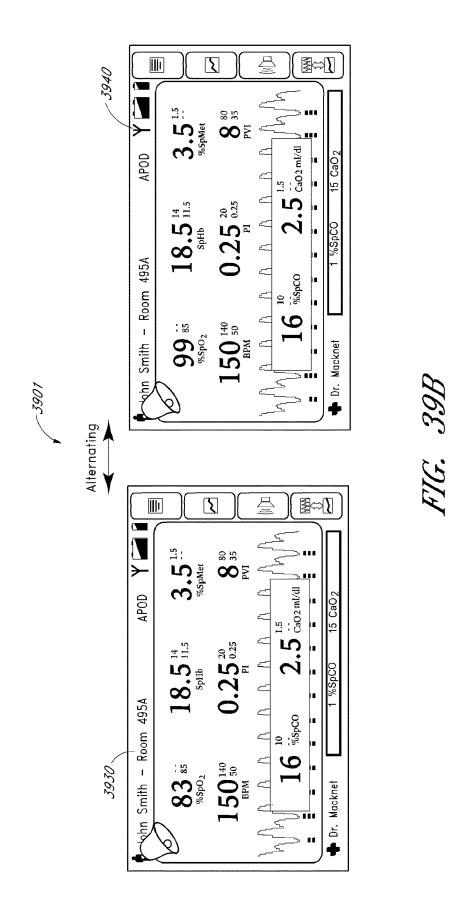


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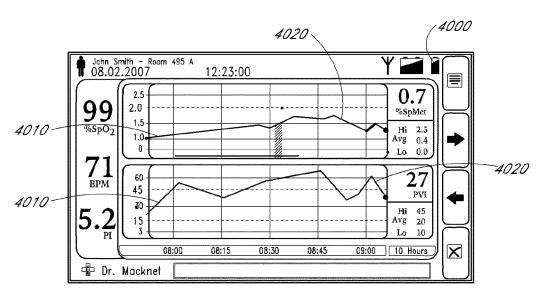


FIG. 40A

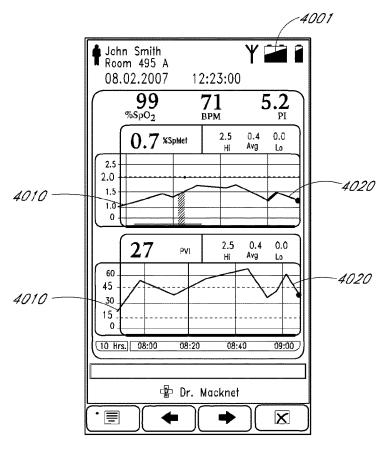


FIG. 40B

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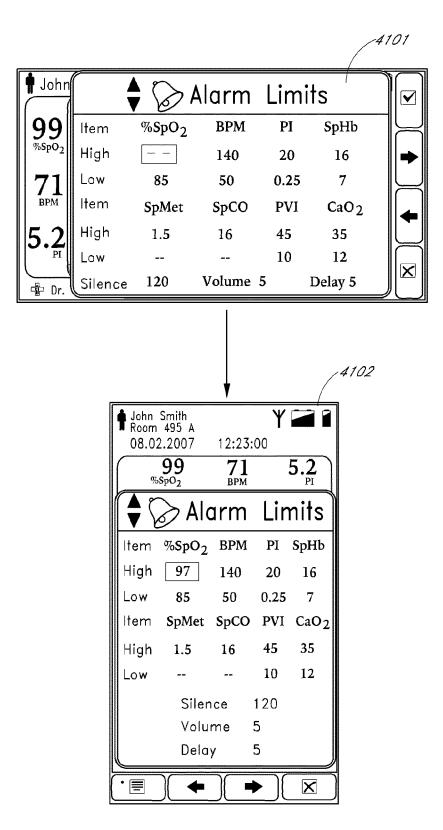
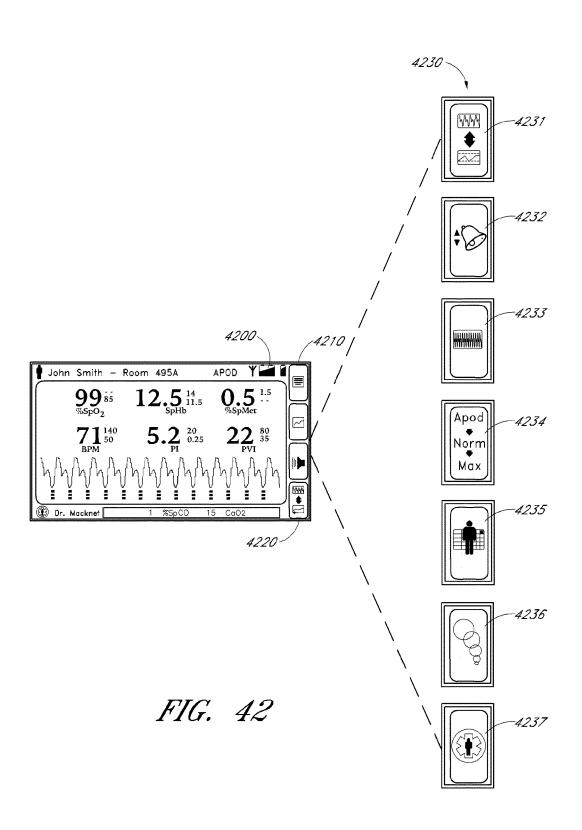


FIG. 41

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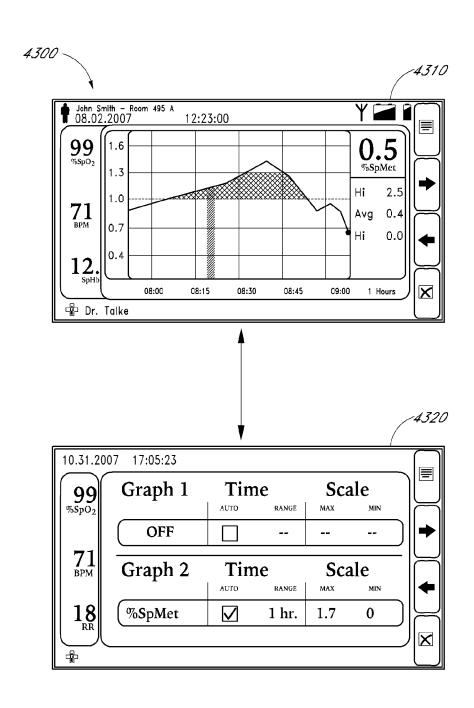
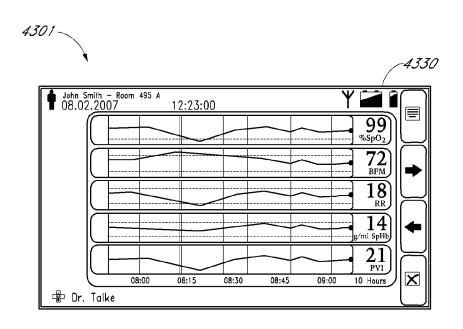


FIG. 43A

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					/	-434		
10.31.2007 17:05:23								
99	Graph 5 Up	Ti:	me range	Sca MAX	lle MIN			
%SpO ₂	(%SpO ₂		1 hr.	1.7	0			
71	BPM		1 hr.	1.7	0			
BPM	Off							
1.0	Off							
18 RR	OFF							

FIG. 43B

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PHYSIOLOGICAL PARAMETER ALARM DELAY

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. patent application Ser. No. 14/975,564, filed Dec. 18, 2015, entitled "MEDICAL COMMUNICATION PROTOCOL TRANS-LATOR," which is a divisional of U.S. patent application 10 Ser. No. 12/717,081, now U.S. Pat. No. 9,218,454, filed Mar. 3, 2010, and entitled "MEDICAL MONITORING SYSTEM," which claims a priority benefit to U.S. Provisional Application No. 61/209,147, filed Mar. 4, 2009, and entitled "PROXIMITY DISPLAY MONITOR," and to U.S. Provisional Application No. 61/296,439, filed Jan. 19, 2010, and entitled "MEDICAL MONITORING SYSTEM," the entire contents of each of which are hereby incorporated by reference herein.

BACKGROUND

Field of the Invention

This disclosure relates to systems, devices, and methods with applications in, for example, hospitals and other patient 25 care facilities. For example, the systems, devices, and methods described herein can be used for acquiring physiological information from patients, analyzing the physiological information, and communicating the physiological information to clinicians and other systems or devices.

Description of the Related Art

Hospitals, nursing homes, and other patient care facilities typically include patient monitoring devices at one or more bedsides in the facility. Patient monitoring devices generally include sensors, processing equipment, and displays for 35 obtaining and analyzing a medical patient's physiological parameters. Physiological parameters include, for example, respiratory rate, SpO₂ level, pulse, and blood pressure, among others. Clinicians, including doctors, nurses, and certain other medical personnel use the physiological parameters obtained from the medical patient to diagnose illnesses and to prescribe treatments. Clinicians also use the physiological parameters to monitor a patient during various clinical situations to determine whether to increase the level of medical care given to the patient.

Patient monitors capable of measuring pulse oximetry parameters, such as SpO2 and pulse rate in addition to advanced parameters, such as HbCO, HbMet and total hemoglobin (Hbt) and corresponding multiple wavelength optical sensors are described in at least U.S. patent appli- 50 cation Ser. No. 11/367,013, filed Mar. 1, 2006 and entitled Multiple Wavelength Sensor Emitters and U.S. patent application Ser. No. 11/366,208, filed Mar. 1, 2006 and entitled Noninvasive Multi-Parameter Patient Monitor, both assigned to Masimo Laboratories, Irvine, Calif. (Masimo 55 Labs) and both incorporated by reference herein. Further, noninvasive blood parameter monitors and corresponding multiple wavelength optical sensors, such as RainbowTM adhesive and reusable sensors and RAD-57TM and Radical-7TM monitors for measuring SpO2, pulse rate, perfusion 60 index, signal quality, HbCO and HbMet among other parameters are also available from Masimo Corporation, Irvine, Calif. (Masimo).

Advanced physiological monitoring systems may incorporate pulse oximetry in addition to advanced features for 65 the calculation and display of other blood parameters, such as carboxyhemoglobin (HbCO), methemoglobin (HbMet)

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and total hemoglobin (Hbt), as a few examples. Advanced physiological monitors and corresponding multiple wavelength optical sensors capable of measuring parameters in addition to SpO2, such as HbCO, HbMet and Hbt are described in at least U.S. patent application Ser. No. 11/367, 013, filed Mar. 1, 2006, titled Multiple Wavelength Sensor Emitters and U.S. patent application Ser. No. 11/366,208, filed Mar. 1, 2006, titled Noninvasive Multi-Parameter Patient Monitor, assigned to Masimo Labs and incorporated by reference herein. Further, noninvasive blood parameter monitors and corresponding multiple wavelength optical sensors, such as RainbowTM adhesive and reusable sensors and RAD-57TM and Radical-7TM monitors for measuring SpO2, pulse rate, perfusion index (PI), signal quality (SiQ), pulse variability index (PVI), HbCO and HbMet among other parameters are also available from Masimo.

SUMMARY OF THE INVENTION

Various medical monitoring devices, systems, and methods are described herein. In some embodiments, a medical monitoring device or system is capable of detecting the presence of a clinician and, for example, taking some action in response to detection of the clinician's presence. In some embodiments, a medical monitoring system is capable of detecting the location of a number of medical devices, clinicians, and/or patients in a hospital or other patient care facility. The detected locations can then be used to take some location-based action, such as, for example, changing the configuration of a medical device.

Various devices, systems and methods for facilitating communication between medical monitoring devices or systems using a medical communication protocol translator are described herein. A medical communication protocol translator can be configured to facilitate communication between medical devices that are programmed to communicate with different protocol formats. The medical communication protocol translator can receive an input message formatted according to a first protocol format from a first medical device and to output an output message formatted according to a second protocol format supported by a second medical device using a set of translation rules. For example, a medical communication protocol translator can receive an input message from a hospital information system formatted according to a first HL7 protocol format and output an output message formatted according to a second HL7 protocol format based on a comparison with the set of transla-

In some embodiments, a medical monitoring device or system is capable of collecting physiological parameter data from a number of patients, and using this data to simulate a variety of alarm condition detection criteria and/or alarm notification delay times. These simulated alarm condition detection criteria and/or alarm notification delay times can be analyzed and used to alter actual alarm condition detection criteria and/or alarm notification delay times that are used by, for example, bedside patient monitoring devices.

In certain embodiments, a medical patient monitoring device for monitoring physiological information includes an interface configured to receive physiological information from at least one patient. The device can further include a processor configured to perform a clinically-useful task based on the physiological information. The device can also include a detector for detecting the physical presence of a clinician token within a detection area in the vicinity of the medical patient monitoring device, where the clinician token is indicative of the identity of a clinician. Moreover, the

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processor can be configured to take a first predetermined action in response to detection of the clinician token, where the first predetermined action is associated with the identity of the clinician.

In certain embodiments, a clinical system for determining 5 the physical locations of a plurality of medical devices includes multiple medical patient monitoring devices that are capable of collecting physiological information from multiple patients. The clinical system can further include a distributed network of detectors that are capable of detecting 10 wireless signals from the medical patient monitoring devices. The clinical system can also include a location monitoring server communicatively coupled to the detectors that is capable of determining estimates of the physical locations of the medical patient monitoring devices based 15 upon the wireless signals detected from the detectors.

In various embodiments, a method for facilitating communication between first and second medical devices within a medical information network includes receiving a first input message from a first medical device, where the first 20 input is generated according to a first communication protocol. The input message can identify a second medical device as an intended recipient of the input message. The method can further include translating the input message into an output message by applying one or more translation 25 rules. The method can also include providing the output message to the second medical device, which is configured to receive and process the output message.

In certain embodiments, a medical device message translator configured to facilitate communication between first 30 and second medical devices within a medical information network includes a communication interface module configured to receive a first input message from a first medical device, the first medical device having generated the input message according to a first communication protocol. The 35 input message can identify a second medical device as an intended recipient of the input message. The translator can further include a rules module configured to store one or more predetermined translation rules and a translation module configured to translate the input message into an output 40 message by applying one or more translation rules retrieved from the rules module. The second medical device can be configured to receive and process the output message.

In various embodiments, a method for converting messages communicated between medical devices and a hospital 45 or clinical information system includes receiving an input message from a hospital information system that includes electronic patient medical records, where the content of the input message is formatted according to a first set of formatting rules allowed under a medical electronic com- 50 munication protocol. The method can further include comparing the input message to a set of transformation rules and generating an output message, where the content of the output message is re-formatted according to a second set of formatting rules allowed under the medical electronic com- 55 munication protocol. The transformation rules can control the re-formatting of the content of the output message so as to comply with the second set of formatting rules. The method can also include outputting the output message to a medical device.

In various embodiments, a method of providing field-customizable transformation of input and output medical messages belonging to a common medical electronic communication protocol but having different formats includes receiving an input message from a first medical device, the 65 content of the input message being formatted according to a first set of formatting rules. The method can further include

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determining an intended recipient medical device from the input message. The method can also include comparing the input message to a set of transformation rules and changing the formatting of the input message to reflect a second set of formatting rules expected by the intended recipient medical device based on the comparison of the input message to the set of transformation rules. Moreover, the method can also include generating an output message, the content of the output message being formatted according to the second set of formatting rules, and outputting the output message to the intended recipient medical device.

In certain embodiments, a system for facilitating communication of medical messages between a hospital information system and a patient monitor includes a hospital information system having an electronic medical records database configured to store electronic medical records of patients. The system can further include a patient monitor configured to monitor at least one physiological condition of a patient. The system can also include a transformation module configured to be communicatively coupled between the hospital information system and the patient monitor. The transformation module can be configured to receive an input message from one of the hospital information system or the patient monitor, the content of the input message being formatted according to a first set of formatting rules; compare the input message to a set of transformation rules; and generate an output message, the content of the output message being re-formatted according to a second set of formatting rules, where the transformation rules control the re-formatting of the content of the output message so as to comply with the second set of formatting rules.

In certain embodiments, a system for facilitating communication of medical messages between medical devices over a network includes a first medical device configured to transmit and receive medical messages, the first medical device configured to be communicatively coupled to a network. The system can further include a second medical device configured to transmit and receive medical messages, the second medical device configured to be communicatively coupled to the network. The system can also include a transformation module configured to be communicatively coupled between the first medical device and the second medical device. The transformation module can be configured to receive an input message from the first medical device, where the content of the input message is formatted according to a first set of formatting rules, and to compare the input message to a set of transformation rules. The transformation module can also be configured to generate an output message, where the content of the output message is re-formatted according to a second set of formatting rules, and where the transformation rules control the re-formatting of the content of the output message so as to comply with the second set of formatting rules. Moreover, the transformation module can be configured to output the output message to the second medical device.

In various embodiments, a method of defining formatting of medical communications under a medical electronic communication protocol includes compiling format transformation software, installing the format transformation software, and updating a set of transformation rules within a user-configurable file without recompiling the format transformation software.

In certain embodiments, a method for analyzing physiological parameter monitoring data includes receiving physiological parameter data from multiple patients. The method can further include receiving first physiological parameter alarm data from the patients that is indicative of

alarm conditions experienced by the patients that were detected based upon a first alarm criteria. The method can also include generating second physiological parameter alarm data using a processor, where the second physiological parameter alarm data is indicative of simulated alarm conditions that are detected based upon a second alarm criteria. Moreover, the method can include comparing the first and second physiological parameter alarm data using a processor. In certain embodiments, a computer-readable medium includes instructions that, when read by a computer, 10 ing when to disable a clinician-specific action that had been cause the computer to perform this method for analyzing physiological parameter monitoring data.

In various embodiments, a method for analyzing physiological parameter monitoring data includes receiving physiological parameter data from multiple patients. The 15 method can further include receiving first physiological parameter alarm notification data indicative of physiological parameter alarm notifications generated based upon a first alarm notification delay time. The method can also include tion data using a processor, where the second physiological parameter alarm notification data is indicative of simulated physiological parameter alarm notifications generated based upon a second alarm notification delay time. Moreover, the method can include comparing the first and second physi- 25 ological parameter alarm notification data.

BRIEF DESCRIPTION OF THE DRAWINGS

Various embodiments will be described hereinafter with 30 reference to the accompanying drawings. These embodiments are illustrated and described by example only, and are not intended to limit the scope of the disclosure.

- FIG. 1 is an exemplary block diagram showing a physithe present invention;
- FIG. 2 is an exemplary block diagram showing another embodiment of a physiological monitoring system;
- FIG. 3 is an exemplary block diagram showing a network interface module according to an embodiment of the present 40 invention:
- FIG. 4 is an exemplary flowchart diagram showing a process for context-based communication of physiological information according to an embodiment of the present invention; and
- FIG. 5 is an exemplary block diagram showing an alarm notification system according to an embodiment of the present invention.
- FIG. 6 is a block diagram illustrating an embodiment of a clinical network environment;
- FIG. 7 is a block diagram illustrating a more detailed embodiment of the clinical network environment of FIG. 6;
- FIG. 8A is a flow chart illustrating an embodiment of a process for journaling medical events in a journal database;
- FIG. 8B is a flow chart illustrating an embodiment of a 55 process for correlating data from the journal database and the round-robin database;
- FIG. 9 is a screen shot of an example user interface for monitoring patients in the clinical network environment of FIG. 6;
- FIG. 10 is a perspective view of an advanced patientmonitoring system;
- FIG. 11 illustrates a proximity display in a multi-user environment;
- FIG. 12 is a general block diagram of a proximity display 65 monitor;
 - FIG. 13 illustrates a user display preference screen;

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- FIG. 14 is a schematic diagram of a patient monitoring device that is capable of automatically detecting the presence of a clinician token;
- FIG. 15 is a flowchart illustrating detection method for detecting the presence of a clinician token within the detection region of a patient monitoring device;
- FIG. 16 illustrates an example graphical user interface of nurses' station or a central patient monitoring station;
- FIG. 17 is a flowchart illustrating a method for determinpreviously enabled by a patient monitoring device based upon the detected presence of the clinician;
- FIG. 18 is a schematic diagram of a system for enabling a patient monitoring device to automatically detect the presence of a clinician token;
- FIG. 19 is a schematic illustration of a patient monitoring device network having a clinician proximity awareness feature:
- FIG. 20 is a schematic drawing of a hospital floor with generating second physiological parameter alarm notifica- 20 distributed WiFi access points that can be used to estimate the physical locations of medical devices, patients, and clinicians;
 - FIGS. 21A-F, FIGS. 22A-E, and FIGS. 23A-C illustrate proximity display embodiments that advantageously provide user proximity feedback;
 - FIGS. 21A-F illustrate a proximity display embodiment utilizing a virtual rotating triangular solid for proximity feedback:
 - FIGS. 22A-E illustrate a proximity display embodiment utilizing a virtual rotating cube for proximity feedback;
 - FIGS. 23A-C illustrate proximity display embodiment utilizing a virtual rotating planar solid for proximity feedback:
- FIG. 24A illustrates a first medical device and a second ological monitoring system according to an embodiment of 35 medical device that communicate with one another via a translation module:
 - FIG. 24B illustrates a first medical device and a second medical device that communicate with one another via a translation module and a communication bus;
 - FIG. 25A illustrates an example input message received by the translation module;
 - FIG. 25B illustrates a message header segment of the input message of FIG. 19A that has been parsed into fields;
 - FIG. 25C illustrates an encoded version of the parsed message header segment of FIG. 25B;
 - FIG. 25D illustrates an example output message of the translation module based on the input message of FIG. 25A:
 - FIG. 26 illustrates a translation process for generating an output message based on an input message and a comparison 50 with translation rules associated with the translation module;
 - FIG. 27A illustrates a translation process in which the translation module facilitates communication of an HL7 message from a Hospital Information System ("HIS") having a first HL7 format to an intended recipient medical device having a second HL7 format;
 - FIG. 27B illustrates a translation process in which the translation module facilitates communication of an HL7 message from a medical device having a first HL7 format to a HIS having a second HL7 format;
 - FIG. 28 illustrates an example screenshot from a messaging implementation software tool for manually configuring translation rules to be used by the translation module;
 - FIGS. 29A and 29B illustrate automatic rule configuration processes performed by the translation module;
 - FIGS. 29C and 29D illustrate automatic rule configuration processes performed by the translation module for messages utilizing the HL7 protocol;

-

FIG. 30 is an example graph of the distribution of alarm events for a given physiological parameter as a function of alarm limit values:

FIG. **31** is a flow chart that illustrates a method for determining the variation in identified alarm conditions 5 resulting from varying alarm criteria;

FIG. 32 illustrates an example report with a table showing how simulated alarm criteria affect alarm detection events;

FIG. **33** is a flow chart that illustrates another method for determining the variation in identified alarm conditions that 10 occur as a result of varying alarm criteria;

FIG. 34 illustrates an example report with a table showing how simulated alarm criteria affect the number of alarm detection events as well as how the simulated alarm criteria affect, for example, false negatives and false positives;

FIG. 35 is a flow chart that illustrates a method for determining the variation in alarm notification events that occurs as a result of varying alarm notification delay times;

FIGS. **36**A-B, FIGS. **37**A-F, FIGS. **38**A-B, FIGS. **39**A-B, FIGS. **40**A-B, FIG. **41**, FIG. **42**, and FIGS. **43**A-B illustrate ²⁰ proximity displays that provide advantageous features in multi-user patient-monitoring environment;

FIGS. **36**A-B illustrate displays having layout zones; FIGS. **37**A-F illustrate displays that vary layouts and font sizes according to the number of installed parameters;

FIGS. **38**A-B illustrate displays having parameter wells; FIGS. **39**A-B illustrate displays that enlarge alarming parameters;

FIGS. 40A-B illustrates displays of trend graphs having colored alarm zones;

FIG. 41 illustrate a display that inverts arrow keys to match the cursor:

FIG. 42 illustrates a display having user-selectable jump-screens; and

FIGS. 43A-B illustrate trend graph displays.

DETAILED DESCRIPTION

In various embodiments, physiological monitoring systems are systems that monitor physiological signals gener- 40 ated by a medical patient and process the signals to determine any of a variety of physiological parameters of the patient. For example, in some cases, a physiological monitoring system can determine any of a variety of physiological parameters of a patient, including respiratory rate, 45 inspiratory time, expiratory time, i:e ratio (e.g., inspirationto-expiration ratio), inspiratory flow, expiratory flow, tidal volume, minute volume, apnea duration, breath sounds, rales, rhonchi, stridor, and changes in breath sounds such as decreased volume or change in airflow. In addition, in some 50 cases the physiological monitoring system monitors other physiological sounds, such as heart rate to help with probeoff detection, heart sounds (e.g., S1, S2, S3, S4, and murmurs), and changes in heart sounds such as normal to murmur or split heart sounds indicating fluid overload. 55 Moreover, the physiological monitoring system may use a second probe over the chest for better heart sound detection, keep the user inputs to a minimum (for example, only input height), and use a Health Level 7 (HL7) interface to automatically input demography.

A physiological monitoring system of certain embodiments includes one or more patient monitoring devices connected to a shared network using open architecture communications standards. The patient monitoring devices of certain embodiments include a physiological monitor 65 coupled with a network interface module. The physiological monitor includes one or more sensors and a sensor process-

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ing module for processing signals from the sensors. The network interface module receives physiological information from the sensor processing module and transmits this information over the shared network. The network interface module may connect to a variety of physiological monitors. In addition, the network interface module of various implementations is a portable bedside device assigned exclusively to one medical patient.

In certain embodiments, the network interface module facilitates establishing a network connection directly with end users over the shared network. These end users, including doctors, nurses, and other hospital staff, may receive physiological information, alarms, and alerts from the network interface module on an electronic device, such as a pager, PDA, laptop, computer, computer on wheels (COW), or the like.

Referring to FIG. 1, certain embodiments of a physiological monitoring system 100 (e.g., alarm notification system) include an open network architecture using "off-the-shelf" hardware and communication protocols. This architecture in various implementations is a shared, or open, network includes multiple patient monitoring devices 110, a network bus 120 (e.g., an Ethernet backbone), and a hospital WLAN 126. In addition, the shared network may further include a connection 122 to the Internet 150, to end user devices 152 over the Internet 150, and to end user devices 128 over the hospital WLAN 126. The physiological monitoring system 100 of certain embodiments is therefore an enterprise system that achieves a cost-effective replacement for currently available patient monitoring systems.

The physiological monitoring system 100 includes a plurality of bedside devices, e.g., patient monitoring devices 110. The patient monitoring devices 110 of various embodiments include sensors 102, one or more sensor processing modules 104, and a communications module, e.g., network interface module 106. In the depicted embodiment, two patient monitoring devices 110 are shown. One patient monitoring device includes one set of sensors 102, one sensor processing module 104, and one network interface module 106. The other patient monitoring device 110 includes two sets of sensors 102, two sensor processing modules 104, and one network interface module 106.

In certain embodiments, each patient monitoring device 110 is used by one medical patient. The patient monitoring devices 110 form a network of patient monitoring devices 110, each of which can communicate with clinicians and other end users over a shared network, including a hospital network 126 and network interfaces to the Internet 150.

One or more sensors 102 of the patient monitoring device 110 are attached to a medical patient. These sensors 102 may include ECG sensors, acoustic sensors, pulse oximeters, and other types of sensors. The sensors 102 obtain physiological information from a medical patient and transmit this information to the sensor processing module 104 through cables 103 or through a wireless connection (not shown). In certain embodiments, the physiological information includes one or more physiological parameters or values and waveforms corresponding to the physiological parameters.

The sensor processing module 104 receives physiological
60 information from the sensors 102. The sensor processing
module 104 of certain embodiments includes a circuit having a processor, input ports for receiving the physiological
information, software for processing the physiological information in the processor, an optional display, and optionally
65 an input device (e.g., a keyboard). In addition, the sensor
processing module 104 contains one or more output ports,
such as serial ports. For example, an RS232, RS423, or

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autobaud RS232 (serial interface standard) port or a universal serial bus (USB) port may be included in the sensor processing module 104.

In certain embodiments, the sensor processing module 104 generates waveforms from signals received from the 5 sensors 102. The sensor processing module 104 may also analyze single or multiparameter trends to provide early warning alerts to clinicians prior to an alarm event. In addition, the sensor processing module 104 in certain embodiments generates alarms in response to physiological 10 parameters exceeding certain safe thresholds.

Example alerts include no communication with pulse oximeter, alarm silenced on pulse oximeter, instrument low battery (pulse oximeter), and transmitter low battery. Example alarms include SpO₂ levels and alarms, high and low SpO₂, high and low PR, HbCO level and alarms, HbMET level and alarms, pulse rate and alarms, no sensor, sensor off patient, sensor error, low perfusion index, low signal quality, HbCO, HbMET, PI trend alarm, and desat index alarm.

The network interface module 106 in the depicted embodiment is connected to one or more sensor processing modules 104 through one or more connectors 108, which may be serial connectors corresponding to the serial ports in the sensor processing modules 104. Dashed lines on the 25 connector 108 indicate that the network interface module 106 of certain embodiments is not permanently attached to the sensor processing modules 104. In alternative embodiments (not shown), however, the network interface module 106 is contained within a sensor processing module 104.

The network interface module 106 in various implementations includes a processor, an input port (such as a standard RS232 serial port), a network output port such as an Ethernet port, and software which enables the network interface module 106 to act as a network-communications enabled 35 device. In addition, the network interface module 106 includes a storage device 114, which may be included within the network interface module 106 or attached separately to the network interface module 106.

The network interface module 106 manages the connec- 40 tivity overhead for initiating and maintain connectivity with end user devices over the shared network. In certain embodiments, the network interface module 106 manages connectivity by acting as a microserver or web server. In such instances, the network interface module 106 is a network 45 connection enabled device. As a web server, the network interface module 106 establishes direct connections to the Internet 150, such that an end user may access web pages stored on the storage device 114 of the network interface module 106. In one embodiment, the network interface 50 module 106 therefore does not require a separate server for connecting to the Internet 150. In one embodiment, the network interface module 106 connects to the Internet 150 directly through a modem, such that the connection 122 includes a modem. In managing connectivity over the shared 55 network, the network interface module 106 may also perform security management functions, such as user authentication.

In certain embodiments, the network interface module 106 sends data over the shared network through an access 60 point 124 or other wireless or wired transmitter. Alternatively, the network interface module 106 may communicate physiological information directly to end users over the Internet 150. End users such as clinicians carrying notifier devices, e.g., end user devices 128, 152 connected to the 65 hospital WLAN 126 may receive real-time viewing of physiological patient parameters and waveforms on demand

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or in the event of an alarm or alert. Real-time or slightly delayed transmission of physiological information in certain embodiments comports with standards for alarm latency in compliance with Joint Commission on Accreditation of Healthcare Organizations (JCAHO) standards for effective alarm response. The network interface module 106 of certain embodiments therefore adds functionality equivalent to a central nurses' station.

In certain embodiments, the network interface module 106 performs context management. In one embodiment, context management includes associating context information with physiological information to form a contextual data package. Context information may include several categories of information, including the categories of context information related to the network interface module 106, context information related to the medical patient, context information related to usage of the network interface module 106, and context information related to a network 20 connection. Within one or more of these context categories, context information might include a patient name, a patients' unique hospital identification number, patient location, an identification number for a network interface module 106, time stamps for events occurring in the physiological monitoring system 100, environmental conditions such as changes to the state of the network and usage statistics of the network interface module 106, and identification information corresponding to the network link (e.g., whether the network connection is WiFi or Ethernet). In one embodiment, the context information in the contextual data package may include all of or any subset of context information from one or more of the context categories.

The network interface module 106 receives context information, for example, by a nurse entering the information in the network interface module 106 or from a server 136. In one embodiment, by receiving this information (including, e.g., patient identification number and location), the network interface module 106 becomes exclusively assigned to the medical patient. The network interface module 106 transmits or communicates the contextual data package to clinicians during an alarm or alert, upon clinician request, or on a scheduled basis. In addition, the network interface module 106 may transmit a continuous stream of physiological information to clinicians.

By optionally connecting to multiple sensor processing modules 104 in certain embodiments, the network interface module 106 is able to associate patient context information and other context information with multiple sensor processing modules 104. Consequently, context can be created for one or more sensor processing modules 104 in addition to context being created for the network interface module 106.

In addition to transmitting the contextual data package, the network interface module 106 in one embodiment stores the contextual data package in the storage device 114. The storage device 114 may be a flash memory, a hard disk drive, or other form of non-volatile or volatile memory. In certain embodiments the storage device 114 acts as a flow control buffer. The network interface module 106 uses the storage device 114 acting as a flow control buffer to perform flow control during communications, as explained more fully below in connection with FIG. 3.

In some implementations, a server 136 may optionally be included in the physiological monitoring system 100. The server 136 in these implementations is generally a computing device such as a blade server or the like. In certain embodiments, the server 136 is an appliance server housed

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in a data closet. In other embodiments, the server 136 is a server located at a central nurses' station, such as a work-station server.

The server 136 receives contextual data packages from a plurality of network interface modules 106 and stores the 5 contextual data package in a storage device 138. In certain embodiments, this storage device 138 therefore archives long-term patient data. This patient data may be maintained even after the patient is discharged. In storing patient data, the server 136 may act as an interface between the shared 10 network and an external electronic medical record (EMR) system.

The server 136 may also store data concerning user interactions with the system and system performance metrics. Integrated into the server 136 of certain embodiments 15 is a journal database that stores every alert and alarm or a subset of the alerts and alarms as well as human interaction in much the same way as an aviation "black box" records cockpit activity. The journal is not normally accessible to the clinical end user and, without technical authorization, cannot 20 be tampered with. In addition, the server 136 may perform internal journaling of system performance metrics such as overall system uptime.

In one embodiment, the journaling function of the server 136 constitutes a transaction-based architecture. Certain 25 transactions of the physiological monitoring system 100 are journaled such that a timeline of recorded events may later be re-constructed to evaluate the quality of healthcare given. These transactions include state changes relating to physiological information from the patient monitoring devices 30 100, to the patient monitoring devices 110, to the hospital WLAN 126 connection, to user operation, and to system behavior. Journaling related to the physiological information received from a physiological monitor in one embodiment includes recording the physiological information itself, 35 recording changes in the physiological information, or both.

The server 136 in certain embodiments provides logic and management tools to maintain connectivity between network interface modules 106, clinician notification devices such as PDAs and pagers, and external systems such as 40 EMRs. The server 136 of certain embodiments also provides a web based interface to allow installation (provisioning) of software rated to the physiological monitoring system 100, adding new devices to the system, assigning notifiers (e.g., PDAs, pagers, and the like) to individual clinicians for alarm 45 notification at beginning and end of shift, escalation algorithms in cases where a primary caregiver does not respond to an alarm, interfaces to provide management reporting on the alarm occurrence and response time, location management, and internal journaling of system performance metrics 50 such as overall system uptime (see, e.g., FIG. 5 and accompanying description).

The server 136 in certain embodiments also provides a platform for advanced rules engines and signal processing algorithms that provide early alerts in anticipation of a 55 clinical alarm. The operating system on the server 136 in one embodiment is Linux-based for cost reasons, though a Microsoft-based or other operating system may also be used. Moreover, the server 136 is expandable to include data storage devices and system redundancy capabilities such as 60 RAID (random array of independent disks) and High Availability options.

In another embodiment (not shown), end user devices 128, 152 include one way POCSAG Pagers having a 2 line display with audible and vibrate mode, of suitable size and 65 durability for severe mechanical environments typical of hospital general floor settings. In yet another embodiment,

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the end user devices 128, 152 include two way paging systems, such as Motorola Flex and WLAN pagers. One advantage of two-way paging is the ability to confirm message receipt and the ability to remotely silence alarms. Wireless PDAs may also be used by end users based on ruggedness and acceptable form factors as determined by an end user. An example of such a device is the Symbol Technology MC50 PDA/Barcode Scanner.

FIG. 2 depicts another embodiment of the physiological monitoring system 200 of the present invention. The physiological monitoring system 200 includes network communications enabled devices 210. The network communications enabled devices 210 are connected directly to a hospital network 220 through a wireless connection. In certain embodiments, the network communications enabled devices 210 include sensors and sensor processing modules, similar to the sensors 102 and sensor processing modules 104 of FIG. 1. Certain of these network communications enabled devices 210 are bedside devices, and others are handheld or otherwise patient-worn devices that may be used by an ambulatory (mobile) patient.

The hospital network 220 transmits physiological information and context information to clinician notifier devices, including pagers 240, PDAs 230, and the like. In certain embodiments, the hospital network 220 utilizes a server 250 to transmit contextual data packages to a page transmitter 242, which further transmits the data to one-way wireless pagers 240. An external interface 280 may be coupled with the server 250. The external interface 280 could include one or more of the following: enterprise paging, nurse call systems, wide area paging systems, enterprise clinical and patient information systems, and third party monitoring and surveillance systems.

Certain other devices 260, such as some patient monitoring equipment, are not network communications enabled devices. That is, these other devices 260 are unable to connect to a network unaided. In the depicted physiological monitoring system 200, example devices 260 that are not network communications enabled are connected to a network interface module 270. The network interface module 270 is connected to the non-network communication enabled other devices 260 through RS232 cables 264. Such a connection is a standardized serial connection found on many devices. Because the network interface module 270 has an RS232 port, the network interface module 270 can allow non-network communication enabled patient monitoring devices to connect directly to the hospital network 220 and also to the Internet.

Moreover, by connecting to one or more other devices 260 in some embodiments, the network interface module 270 is able to associate patient context information and other context information with one or more other devices 260. Consequently, context can be created for one or more other devices 260 in addition to context being created for the network interface module 270.

FIG. 3 depicts a network interface module 300 in accordance with certain embodiments of the present invention. The network interface module 300 in the depicted embodiment includes an input port 302, which in certain embodiments is a serial port for facilitating a connection to a sensor processing module. The network interface module 300 also includes a network interface 304, which may be a wired interface (e.g., Ethernet) or a wireless interface such as WiFi, Bluetooth, or the like. Alternatively, the network interface module 104 may communicate through a cable TV interface or other type of interface. Such a CTV interface provides a

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subcarrier bi-directional communications capability that would simultaneously co-exist with video formats.

The network interface module 300 also communicates with a storage device 350. While in the depicted embodiment the storage device 350 is shown as separate from the 5 network interface module 300, in some implementations the storage device 350 is part of the network interface module 300. In addition, though not shown, the network interface module 300 may include a processor for implementing communications program code. Similarly, though not 10 shown, the network interface module 300 may include an input device for a nurse to input context information and a display for receiving output from the network interface module 300.

The network interface module **300** can be integrated into 15 handheld, portable or stationary patient monitoring platforms or instruments or contained in an accessory package with an RS232 input for general interface to such devices. In another embodiment, (not shown) active RFID tag capabilities are included with the network interface module **106**, 20 with the clinician devices (e.g., notifier devices), or with both so that either a patient or a clinician can be located when an event occurs or on request. When operating on a shared network, the network interface module **106** is also compliant with to the open architecture communications 25 standards of IEEE 802.1X (security and authorization), IEEE 802.3 (Ethernet), and WiFi (IEEE 802.11 a, b, g, e, i wireless protocols).

A context management module 310 in the network interface module 300 manages context data. In one embodiment, 300 the context management module 310 receives context information, such as the context information described in connection with FIG. 1 above. In one embodiment, a nurse or other clinician enters context information, such as patient name, identification number, and location, into the network 35 interface module 300 via a keyboard or other input device (not shown) when the patient is admitted to the hospital or assigned a particular bed in the hospital. In other embodiments, the context management module 310 receives the context information from a server, such as the server 136 of 40 FIG. 1.

The context management module 310 associates the context information with physiological information received from a sensor processing module. In certain embodiments, the context management module 310 performs this association when an alarm condition occurs. In such instances, the context management module 310 may create a contextual data package including a snapshot of historical physiological information together with the context information. In other embodiments, the context management module 310 performs an association continuously, and the network interface module 300 sends continuous or scheduled contextual data packages to end users. In addition, the context management module 310 or other modules in the network interface module 300 store the contextual data package in the storage 55 device 350.

The communications module 320 uses the network interface 304 to communicate with a network. In certain embodiments, the communications module 320 possesses the functionality of a web server. As a web server, the 60 communications module 320 enables the network interface module 300 to communicate with a hospital network and the Internet directly, without using a server. Consequently, other devices such as physiological monitoring devices that are not network connection enabled may connect with the 65 network interface module and thereby become network enabled. The network interface module 300 manages the

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connectivity overhead for initiating and maintaining connectivity, manages context information (e.g., any of the context information described above in connection with FIG. 1), and provides a web server for displaying patient information on web-enabled devices. In one embodiment, a communications protocol based on XML technologies allows bedside devices to interface to a multitude of target end user platforms including PDAs, computer on wheels (COW), Tablet PCs, IP cell phones (smartphones), and fixed PCs.

In certain embodiments, the communications module 320 uses standard communications protocols to communicate with a network. Some examples of standard communications protocols include Ethernet, WiFi (WLAN), Bluetooth, and the like. By using standard communications protocols, the communications module 320 is able to send and receive data over a shared network or open network architecture. However, the communications module 320 may also be used on a proprietary network using proprietary protocols.

In embodiments where the network interface module 300 communicates over a shared network rather than a proprietary network, the network interface module 300 shares network resources with other devices on the network. In some cases, high-volume network traffic affects the reliability of network communications. Consequently, certain implementations of the network interface module 300 include a flow control module 330. The flow control module 330 verifies that transmitted data was received by an end user. In the event that the end user did not receive the data, the flow control module 330 resends the data stored in the storage device 350. In certain embodiments, the storage device 350 therefore acts as a flow control buffer.

A security module 340 manages user access to the network interface device 300 and to data stored in the storage device 350. In certain embodiments, the security module 340 determines whether a user attempting to connect to the network interface module 300 is authorized to do so. In one implementation, the security module 340 uses the standard IEEE.802.1X network access control protocol to manage authentication. The network interface module 106 in certain embodiments provides security and encryption to meet the Health Insurance Portability and Accountability Act (HIPAA) requirements.

In certain embodiments, the network interface module 300 incorporates all or a portion of the functionality specified by the IEEE 1073 standard and the most recent update to the IEEE 1073 standard, namely the IEEE 11703 standard, both of which are hereby incorporated by reference. In certain embodiments, the context management module 310, the communications module 320, the flow control module 330, and the security module 340 also incorporate functionality specified in the IEEE 1073 and 11703 standards. By using standard protocols, the network interface module 300 may be used to enable network communication for a wide variety of physiological monitoring devices.

FIG. 4 depicts a process 400 for context-based communication of physiological information according to an embodiment of the present invention. In certain embodiments, the process 400 is performed by any of the network interface modules described above in connection with FIGS. 1-3. In addition, the process 400 in certain embodiments may be performed by any of the physiological monitoring systems described in connection with FIGS. 1, 2, and 5.

The process 400 begins by receiving context information at 402. In one embodiment, a device such as a network interface module receives the context information once, such as in an initialization step. The process 400 then

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receives physiological information at 404. In certain embodiments, the process 400 continues to receive physiological information throughout the remaining steps of the process 400. Alternatively, the process 400 may receive physiological information 400 for a portion of the process 5400

At 405, the process 400 determines whether an alarm condition or alert has occurred. If an alarm condition or alert has occurred, the process 400 proceeds to 406. However, if an alarm condition or alert has not occurred, the process 400 10 loops back to 404. In one embodiment, the looping back of the process 400 to 404 represents that a network interface module continually receives physiological information until an alarm condition or alert occurs. In certain embodiments (not shown), the process 400 may continue to receive 15 physiological information even when an alarm condition or alert occurs.

At 406 the process 400 prepares a contextual data package. The contextual data package may include context information and a snapshot of physiological information. In 20 one embodiment, the snapshot of physiological information includes the physiological information that gave rise to an alarm or alert. In one embodiment, the snapshot of physiological information includes information both before and after the occurrence of an alarm or alert. The contextual data 25 package is stored in a flow control buffer at 408.

At 410, the process 400 establishes a network connection. In one embodiment, establishing a network connection at 410 includes connecting a network interface module to an end user device, such as a notifier device assigned to a nurse 30 during his or her work shift. The process 400 then determines at 412 whether the user of the device (e.g., the nurse) has been authenticated. If the user has not been authenticated, the process 400 proceeds to 420. On the other hand, if the user has been authenticated, the process 400 proceeds 35 to 414.

The process 400 at 414 communicates the contextual data package to the user. At 416, the process 400 determines whether the contextual data package was received. If the contextual data package was received, the process 400 40 proceeds to 420. Otherwise, the process 400 proceeds to 418, where the process 400 accesses data stored in the flow control buffer. In one embodiment, the data accessed by the process 400 is equivalent to or substantially equivalent to the contextual data package communicated to the user at 414.

The process 400 then loops back to 414, where the process 400 communicates (e.g., resends) the contextual data package to the user, and then at 416 re-verifies that the package was received. The process 400 in some implementations continues to loop between steps 414, 416, and 418 50 until the contextual data package was received. Thus, steps 414, 416, and 418 in certain embodiments constitute flow control performed by the process 400. These flow control steps allow the process 400 to overcome network transmission errors which may occur in shared networks.

If the contextual data package was received, the process 400 evaluates whether to continue the monitoring of physiological information at 420. If the process 400 determines to continue monitoring, the process loops back to 404, where the process 400 continues to receive physiological information. If, however, the process 400 determines not to continue monitoring, the process 400 ends.

In various embodiments of the process 400, the contextual data package or the physiological information alone is transmitted to the user even in the absence of an alarm 65 condition. In still other embodiments, fewer than all of the steps are performed, or the steps are performed in different

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order. For instance, the process 400 may only perform the steps of receiving physiological information at 404, preparing a contextual data package at 406, establishing a network connection at 410, and communicating the contextual data package to the user at 414.

FIG. 5 depicts an alarm notification system 500 in accordance with certain embodiments of the present invention. A clinical subsystem 510 defines the major software components of alarm notification system 500 including a clinical assignment module 512, a bedside device initialization module 514, a notification and viewing module 516, an escalation rules module 518, a clinical report module 520, and a clinical data stores module 522. An authentication feature is built into mobile computing devices in compliance with HIPAA and hospital IT policies.

The clinical assignment module 512 has an assignment function. A nursing supervisor assigns individual nurses to specific patients at the start of each shift and upon admission of new patients. Shift assignments take place at change of shift during a "report" transition exercise where individual nurses and nursing supervisor from previous shift "hand off" patients to the next shift. The report can be either formal where all nurses attend or informal dependent on hospital nursing service policies and procedures. The clinical assignment module 512 provides an intuitive interface that allows a listing of available nurses to be assigned individual patients. The major user of this module is the unit clerk as assigned by the nursing supervisor. A nurse can be assigned one or more patients or all patients. An alternative work flow is self assignment where individual nurses assign patients themselves in which case they perform functions of the unit clerk. In the self assignment model, a default is implemented where any unassigned patient is either assigned to all nurses or the nursing supervisor.

The bedside device initialization module **514** has bedside devices, such as the network interface modules described above, that are sometimes set up by an aide to the nurse. In the case where the nurse performs this task, she or he performs the functions of the nursing aide. Work flow includes delivering a device to bedside, applying sensors, initializing the device, and setting patient context, such as name, ID and location.

The notification and viewing module **516** assigns a wireless notification device, such as a one-way pager, PDA, IP telephone, COW, or Tablet to individual nurses. The device becomes associated with her or him. Alarms are routed to the notification device based on the clinical assignment module **512**. Non-dedicated notifier solutions such as hospital owned paging systems issued to nurses have unknown latency characteristics. A general purpose interface is available at the server with a latency of less than 1 second upon receipt from the bedside device and is time stamped upon presentation to the server external interface and stored in a journaling system within the server. An additional interface for mobile computing platforms such as PDA, COWS, and Tablets allows viewing of current and trend data for an individual patient.

The escalation rules module **518** has a rules engine that actuates an escalation policy defined by the hospital. The escalation rules module **518** provides alternative routing of alarms to alternative and additional clinical users in the event an alarm is not responded to or persists for a predefined (e.g., by a policy) period of time. The escalation rules module **518** in certain embodiments routes alarms to an emergency response team.

The clinical report module **520** provides predefined formatted reports on the clinical data from which to determine

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physiologic condition and/or progress. More than one report may be dependent on end user needs. Reports are not time critical views of individual patients and may be remotely viewed by clinicians who have alarm notification system 500 privileges and have been authenticated by the alarm 5 notification system 500. These reports are web browser views that allow clinicians to set viewing parameters such as time and parameter scales and alarm review.

The clinical data stores module **522** provides data storage and database resources to store information as known to 10 those skilled in the art.

Further shown in FIG. 5, a technical support subsystem 530 is isolated from the clinical subsystem 510 in compliance with HIPAA and as such does not allow viewing or access to any patient information with the exception of the 15 risk report module 538. The technical support subsystem 530 includes a provisioning module 532, an administration module, a service module 536, a risk report module 538, and a technical data store module 540.

The provisioning module **532** provides provisioning, 20 which is the initial installation of the system and first customer use. The primary user of the provisioning module **532** is the field installer. The provisioning module **532** contains all the start up scripts and system configurations to bring the system from shipping boxes to full alarm notification system **500** functionality. Provisioning includes steps to configure individual devices, notifiers such as pagers, PDA, COW, Tables and IP telephone at the customer site, preferably by wireless means (e.g., Bluetooth).

The administrative module **534** provides a system interface for the application administrator to set up users, set policies for various actor privileges such as a nurses aide being able to set or change alarms, set up allowed device connection identifications, and other general systems administrative duties typical of IT systems.

The service module **536** provides interfaces for various technical support actors including remote service, IT Service, and Biomed Service. Each of these actors may perform each others' functions. Interfaces allow the service actors to access system performance data to access performance, for 40 example, data traffic, device assets connected, software version management, CPU loading, network loading, etc. and execute remote technical service procedures, for example, resetting a printer queue, repartition of disk, uploading software patches, etc. The service module **536** 45 includes a full journaling function that stores every user interaction or a portion of user actions that can be captured by the system, especially changes in default values or alarm settings.

The risk report module **538** provides summary reports on 50 alarm occurrences, duration of alarm, clinical response time to alarms and other statistical data to determine overall effectiveness of clinical response to alarms in compliance with JCAHO, other regulatory bodies, and internal quality assurance committees.

The technical data stores module **540** has the same characteristics as the clinical data stores module **522** except that the technical data stores module **540** is used for technical data. The technical data stores module **540** may or may not share the same physical and logical entity as the clinical 60 data stores module **522**.

Additionally shown in FIG. 5, an external interface subsystem 550 provides interfaces to bedside devices and external systems such as electronic medical records, admit discharge, transfer systems, POCSAG pager systems, 65 middleware engines such as Emergin, and Web/XML enabled devices such as wireless PDAs, COWs and Tablet

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PCs. The external interface subsystem **550** has an HL7 interface **552**, a pager interface **554**, an XML/Web interface **556**, and a device interface **558**.

The HL7 interface 552 provides a bi-directional interface to electronic medical records (EMR) and supports both push and pull models. The push model is when a bedside nurse initiates data transfer. The pull model is when an EMR system polls the alarm notification system 500 server. The pager interface 554 provides output to external paging system. Message latency is identified to an end user for any user-owned paging solution. This same output can be used for middleware alarm notification systems such as Emergin. The XML/Web interface 556 provides bi-directional interface with mobile computing platforms such as wireless PDA, COWs, Tables, and Web-enabled IP phones. Mobile computing platforms support Web Browser XML applications. The device interface 558 provides a bi-directional interface to bedside devices as well as to other devices enabled by the communications module or accessory. Application Programmer Interface (API) capability is an option for interfacing to other bedside devices.

The major end users of the alarm notification system 500 system (not shown or described for simplicity) include hospital electronic medical records, admit discharge transfer, pharmacy, clinical information, patient flow tracking and others. Actors, e.g., users of the alarm notification system 500, including clinical actors and technical support actors. The clinical actors include nursing supervisors, unit clerks, nursing aides, nurses, rapid response teams and respiratory therapists.

A nursing supervisor assigns individual nurses to specific patients at the beginning of each shift. Shift can vary according to hospital staffing policies. A unit clerk takes direction from the nursing supervisor, typically inputs assignments into system and monitors overall system. A unit clerk may not be available for all shifts. A nursing aide takes assignments from nurse or nursing supervisor, typically applies bedside device sensor, initializes the bedside device and sets alarms to default values. A nurse has primary response to alarms. The nurse is assigned by nursing supervisor to more than one patient dependent on her/his skills and patient needs and is not always assigned the same patient. Nursing aides are not found in all hospitals.

A rapid response team responds to clinical emergencies initiated by either a bedside nurse or a nursing supervisor. The team supports more than one care unit and has one or more members depending on shift. Rapid Response Teams may not be implemented in all hospitals. A respiratory therapist has responsibilities for management of respiratory care for more than one patient and usually more than one care unit. Respiratory therapists are not found in some international settings.

Clinical actor performance substitution allows a high capability actor to assume the roles of other actors. Alarm notification system 500 allows mechanisms for such performance. For example, a nursing supervisor may perform functions of a unit clerk nursing aide, a nurse and a rapid response team. A nurse may perform functions of a unit clerk, a nursing aide and a rapid response team. In some international markets a nurse may perform the functions of a respiratory therapist.

The technical support actors include field installers, application administrators, remote services, IT engineers, biomedical engineers and risk managers. A field installer provisions the system for initial installation, installs components, and validates that the installation and configu-

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ration meet a purchasing contract. An application administrator sets up and maintains user accounts and systems defaults. A remote service provides remote diagnostics and system maintenance over a remote link, such as dial up and VPN. An IT engineer provides network support services if 5 the system is integrated with the hospital IT network. A biomedical engineer provides bedside and system primary service. A risk manager reviews reports for quality and risk mitigation purposes. Technical support actors may also fill in for other actors. For example, an IT engineer, a biomedical engineer, or a remote service can perform the functions of an application administrator. An IT engineer or a biomedical engineer can perform each other's functions.

In certain embodiments, systems and methods are provided for rapidly storing and acquiring physiological trend 15 data. For instance, physiological information obtained from a medical patient can be stored in a round-robin database. The round-robin database can store the physiological information in a series of records equally spaced in time. Parameter descriptors may be used to identify parameter values in 20 the records. The parameter values can be dynamically updated by changing the parameter descriptors to provide for a flexible database. In addition, the size of files used in the database can be dynamically adjusted to account for patient condition.

Additionally, in certain embodiments, medical data obtained from a clinical network of physiological monitors can be stored or journaled in a journal database. The medical data can include device events that occurred in response to clinician interactions with one or more medical devices. The 30 medical event data may also include device-initiated events, such as alarms and the like. The medical data stored in the journal database can be analyzed to derive statistics or metrics, which may be used to improve clinician and/or hospital performance.

As used herein the terms "round-robin database" and "RRDB," in addition to having their ordinary meaning, can also describe improved database structures having unique characteristics and features disclosed herein. Sometimes these structures are referred to herein as dynamic RRDBs or 40 adaptive RRDBs.

FIG. 6 illustrates an embodiment of a clinical network environment 600. The clinical network environment 600 includes a multi-patient monitoring system (MMS) 620 in communication with one or more patient monitors 640, 45 nurses' station systems 630, and clinician devices 650 over a network 610. In certain embodiments, the MMS 620 provides physiological data obtained from the patient monitors 640 to the nurses' station systems 630 and/or the clinician devices 650. Additionally, in certain embodiments, 50 the MMS 620 stores physiological information and medical event information for later analysis.

The network 610 of the clinical network environment 600 can be a LAN or WAN, wireless LAN ("WLAN"), or other type of network used in any hospital, nursing home, patient 55 care center, or other clinical location. For ease of illustration, the remainder of this specification will describe clinical environments in the context of hospitals; however, it should be understood that the features described herein may also be employed in other clinical locations or settings. In some 60 implementations, the network 610 can interconnect devices from multiple hospitals or clinical locations, which may be remote from one another, through the Internet, a leased line, or the like. Likewise, the various devices 620, 630, 640, and 650 of the clinical network environment 100 may be geo-65 graphically distributed (e.g., among multiple hospitals) or co-located (e.g., in a single hospital).

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The patient monitors 640 may be point-of-care (POC) instruments or the like that monitor physiological signals detected by sensors coupled with medical patients. The patient monitors 640 may process the signals to determine any of a variety of physiological parameters. One example of a physiological parameter is blood oxygen saturation (SpO₂). Other examples of physiological parameters are described below with respect to FIG. 7.

The patient monitors **640** can provide the physiological information to the MMS **620**. The patient monitors **640** can also provide information on medical events, such as alarms, to the MMS **620**. Alarms can be triggered, for example, in response to a physiological parameter falling outside of a normal range. Alarms can also include alerts regarding equipment failures, such as a probe-off condition where a sensor has fallen off of a patient. Other examples of medical events are described below with respect to FIG. **7**.

In various embodiments, the patient monitors 640 provide the physiological information and medical events to the MMS 620. The MMS 620 is described in greater detail below. In some implementations, the patient monitors 640 may provide at least some of this information directly to the nurses' station systems 630 and clinician devices 650.

The nurses' station systems **630** can be desktop computers, laptops, work stations, or the like that are located at a nurses' station. One or more nurses' station computers **630** can be located at a single nurses' station. The nurses' station computers **630** can receive and display physiological information and alarm data received from the MMS **620** (or monitors **640**). In certain embodiments, the nurses' station computers **630** use a graphical user interface (GUI) that provides a streamlined, at-a-glance view of physiological and medical information. An example of this GUI is described below with respect to FIG. **9**.

The clinician devices **650** can include any of a variety of devices used by clinicians, such as pagers, cell phones, smart phones, personal digital assistants (PDA), laptops, tablet PCs, personal computers, and the like. The clinician devices **650** are able to receive, in some embodiments, physiological information and alarms from the MMS **620** (or monitors **640**). Physiological and alarm data can be provided to a particular clinician devices **650**, for example, in response to an alarm. The clinician devices **650** can, in some instances, receive values and waveforms of physiological parameters.

The MMS 620 in certain embodiments includes one or more physical computing devices, such as servers, having hardware and/or software for managing network traffic in the network 610. This hardware and/or software may be logically and/or physically divided into different servers 620 for different functions, such as communications servers, web servers, database servers, application servers, file servers, proxy servers, and the like.

The MMS 620 can use standardized protocols (such as TCP/IP) or proprietary protocols to communicate with the patient monitors 640, the nurses' station computers 630, and the clinician devices 650. In one embodiment, when a patient monitor 640 wishes to connect to the MMS 620, the MMS 620 can authenticate the patient monitor 640 and provide the monitor 640 with context information of a patient coupled to the monitor 640. Context information can include patient demography, patient alarm settings, and clinician assignments to the patient, among other things. Examples of context information are described herein. The MMS 620 may obtain this context information from the nurses' station systems 630 or other hospital computer systems, where patient admitting information is provided.

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Upon connecting to a patient monitor **640**, the MMS **620** may receive physiological information and medical events from the patient monitors **640**. The MMS **620** may provide at least a portion of the physiological information and events to the nurses' station systems **630** and/or clinician devices **550**. For example, the MMS **620** may provide physiological data and alarms for a plurality of patient monitors **640** to a nurses' station system **630**, where nurses can evaluate the data and/or alarms to determine how to treat patients. Similarly, the MMS **620** may send wireless pages, emails, 10 instant messages, or the like to clinician devices **650** to provide clinicians with physiological data and alarms.

Advantageously, in certain embodiments, the MMS 620 can store physiological information obtained from the patient monitors 640 in a round-robin database (RRDB) 624. 15 The RRDB 622 of various embodiments includes a streamlined database structure that facilitates rapidly storing and retrieving patient data. The RRDB 622 can therefore be used in certain embodiments to rapidly provide physiological trend data to the nurses' stations 630 and to the clinician 20 devices 650. Thus, for example, if a clinician desires to see a patient's physiological trends over a certain time period, such as the past hour, the clinician can use a nurses' station computer 630 or clinical device 650 to query the MMS 620. The MMS 620 may then obtain physiological information 25 corresponding to the desired time period from the RRDB 622. Advantageously, the RRDB 622 can enable faster acquisition of trend data then is possible with relational databases currently used by hospital monitoring systems. Additional uses and optimizations of the RRDB 622 are 30 described below.

In certain embodiments, the MMS 620 also archives or stores information about medical events in a journal database 624. The medical events can include events recorded by devices such as the patient monitors 640, nurses' station 35 systems 630, and clinician devices 650. In particular, the medical events can include device events that occur in response to a clinician's interaction with a device, such as a clinician-initiated deactivation of an alarm. The medical events can also include device events that occur without a 40 clinician's interaction with the device, such as the alarm itself. Additional examples of medical events are described below with respect to FIG. 7.

The MMS **620** may analyze the medical event information stored in the journal database **624** to derive statistics 45 about the medical events. For example, the MMS **620** can analyze alarm events and alarm deactivation events to determine clinician response times to alarms. Using these statistics, the MMS **620** may generate reports about clinician and and/or hospital performance. Advantageously, in certain 50 embodiments, these statistics and reports may be used to improve the performance of clinicians and hospitals.

For instance, in certain situations, the reports might help hospitals discover the cause of issues with patient monitors **640**. The following example scenario can illustrate potential 55 benefits of such a report. SpO₂ alarm levels tend to be different for adults and neonates. However, some clinicians may not know this and may modify neonate SpO₂ monitors to include adult alarm levels. These changes can result in many false alarms, which may cause clinicians to become 60 frustrated and avoid using the patient monitors **640**. By journaling medical events such as clinician alarm changes, it can be determined by an analysis of the journaled data that clinicians were inappropriately adjusting alarm settings on neonate monitors. A hospital could then use this information 65 to take corrective action, such as by fixing the alarm limits and training the clinicians.

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Although not shown, administrative devices may be provided in the clinical network environment 600. The administrative devices can include computing devices operated by hospital administrators, IT staff, or the like. Using the administrative devices, IT staff may, for example, promulgate changes to a plurality of patient monitors 640, nurses' station systems 630, and the MMS 620. The administrative devices may also allow IT staff to interface third-party systems with the MMS 620, such as electronic medical record (EMR) systems. The third party systems may be used, for instance, to change alarm settings on a plurality of monitors from an administrative device. Actions performed by administrators, IT staff, and administrative devices in general may also be journaled in the journal database 624.

FIG. 7 illustrates a more detailed embodiment of a clinical network environment 700. The clinical network environment 700 includes a network 710, a patient monitor 740, a nurses' station system 730, an MMS 720, an RRDB 722, and a journal database 724. These components may include all the functionality described above with respect to FIG. 6. One monitor 740 and nurses' station system 730 are shown for ease of illustration. In addition, although not shown, the clinician devices 750 described above may also be included in the clinical network environment 700.

The depicted embodiment of the patient monitor 740 includes a monitoring module 742, an RRDB module 744, and a journal module 746. Each of these modules may include hardware and/or software. Other components, such as a communications module, are not shown but may be included in the patient monitor 740 in various implementations.

The monitoring module **742** can monitor physiological signals generated by one or more sensors coupled with a patient. The monitoring module **742** may process the signals to determine any of a variety of physiological parameters. For example, the monitoring module **742** can determine physiological parameters such as pulse rate, plethysmograph waveform data, perfusion index, and values of blood constituents in body tissue, including for example, arterial carbon monoxide saturation ("HbCO"), methemoglobin saturation ("HbMet"), total hemoglobin ("HbT" or "SpHb"), arterial oxygen saturation ("SpO₂"), fractional arterial oxygen saturation ("SpO₂"), oxygen content ("CaO₂"), or the like

In addition, the monitoring module **742** may obtain physiological information from acoustic sensors in order to determine respiratory rate, inspiratory time, expiratory time, inspiration-to-expiration ratio, inspiratory flow, expiratory flow, tidal volume, minute volume, apnea duration, breath sounds, rales, rhonchi, stridor, and changes in breath sounds such as decreased volume or change in airflow. In addition, in some cases the monitoring module **742** monitors other physiological sounds, such as heart rate (e.g., to help with probe-off detection), heart sounds (e.g., S1, S2, S3, S4, and murmurs), and changes in heart sounds such as normal to murmur or split heart sounds indicating fluid overload. Moreover, the monitoring module **742** may monitor a patient's electrical heart activity via electrocardiography (ECG) and numerous other physiological parameters.

In some implementations, the patient monitors 740 may also determine various measures of data confidence, such as the data confidence indicators described in U.S. Pat. No. 7,024,233 entitled "Pulse oximetry data confidence indicator," the disclosure of which is hereby incorporated by reference in its entirety. The patient monitors 740 may also determine a perfusion index, such as the perfusion index described in U.S. Pat. No. 7,292,883 entitled "Physiological

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assessment system," the disclosure of which is hereby incorporated by reference in its entirety. Moreover, the patient monitors **740** may determine a plethysmograph variability index (PVI), such as the PVI described in U.S. Publication No. 2008/0188760 entitled "Plethysmograph 5 variability processor," the disclosure of which is hereby incorporated by reference in its entirety. The parameters described herein are merely examples, and many other parameters may be used in certain embodiments.

In certain embodiments, the RRDB module **744** receives physiological information from the monitoring module **742** and transmits the physiological information over the network **710** to the MMS **720**. In response, the MMS **220** may store the physiological information in the RRDB **722**. Advantageously, in certain embodiments, the RRDB module 15 **744** associates the physiological information with parameter descriptors prior to transmittal to the MMS **720**. The parameter descriptors may be identifiers that the RRDB module **744** associates with each measured physiological parameter value. The MMS **720** may use these parameter descriptors to 20 identify the types of measured parameters received from the RRDB module **744**.

The parameter descriptors may be descriptors generated according to a markup language specification, such as an extensible markup language (XML) specification. As such, 25 the parameter descriptors may include tags that enclose measured physiological values. These tags may be machine readable or human readable. For instance, the tags may include numerical identifiers (e.g., "0017") or descriptive identifiers, such as "SPO2" or "SPHB." A simplified 30 example stream of physiological information from an SpO2 sensor and an SpHb sensor associated with parameter descriptors might be as follows: <SPO2>96</SPO2> <SPHB>14.1</SPHB> <SPO2>97</SPO2> <SPHB>14.0</SPHB>, and so on.

In one embodiment, the RRDB module **744** may have stored (e.g., in a data file) a set of predefined parameter descriptors available for the patient monitor **740**. These parameter descriptors may correspond to possible parameters that may be measured by the patient monitor **740**. The 40 parameter descriptors transmitted by the RRDB module **744** may depend on the particular subset of parameters measured by the patient monitor **740**.

If an additional (or different) parameter is subsequently measured by the patient monitor **740**, the RRDB module **740** 45 may dynamically update the parameter descriptors that are sent to the MMS **720** Likewise, if the patient monitor **740** ceases to measure one of the parameters, the RRDB module **744** may cease to transmit the corresponding parameter descriptor to the MMS **720**.

The patient monitor 740 also includes a journal module 746 in the depicted embodiment. The journal module 740 may record medical events related to the patient monitor 740. These medical events can include clinician-initiated events, such as changes to alarm settings (e.g., maximum 55 and minimum permitted parameter values), types of parameters monitored/sensors connected to the patient monitor 740, and the like. The journal module 746 may record these events by, for example, acting as a key logger or the like to record button presses of a clinician. The journal module 746 60 may also include current-sense circuitry to detect when sensors or cables are connected to the monitor 740, and so forth. The medical events may also include non-clinician initiated events, such as alarms and alerts. The medical events can also include events from administrative devices 65 (not shown), such as EMR updates to alarm settings across the network 710.

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The journal module **746** may log these events locally at the patient monitor **740**. In addition, or instead of logging the events locally, the journal module **746** may transmit information about the events to the MMS **720**. In turn, the MMS **720** can store the event information in the journal database **724**.

The nurses' station system 730 is shown in the depicted embodiment having a patient monitoring client 732. The patient monitoring client 732 can enable the nurses' station system 730 to receive and display physiological information and alarm information. The patient monitoring client 732 includes a user interface module 734. The user interface module 734 may include, for example, software for displaying physiological information, patient information, and medical event information for a plurality of patient monitors 740. The user interface module 734 may also allow clinicians to admit and discharge patients, remotely modify device alarm limits, and the like. An example user interface that may be generated by the user interface module 734 is described below with respect to FIG. 9.

The patient monitoring client 732 further includes a journal module 736. The journal module 736 may include software for recording medical events related to the patient monitoring client 732. For example, the journal module 736 may record which clinicians login to and logoff of the patient monitoring client 732 and when these events occur; admit and discharge events; and other clinician keystrokes, mouse clicks, and interactions with the patient monitoring client 732. The journal module 736 may log this event information locally at the nurse's station system 730 and/or transmit the event information to the MMS 720.

As shown, the MMS 720 may include a network management module 721, an RRDB management module 723, and a journal management module 725, each of which may include one or more software components. In one embodiment, the network management module 721 receives messages containing physiological information and medical event data from the patient monitor 740. The network management module 721 can provide at least a portion of this data to the nurses' station system 730 and clinician devices 650 of FIG. 6. The network management module 721 can also provide the physiological information to the RRDB management module 723 and provide the medical event data to the journal management module 725.

In certain embodiments, the RRDB management module 723 stores the physiological information received from the patient monitor 740 in the RRDB 722. When the patient monitor 740 initially connects to the MMS 720, or at another time, the RRDB management module 723 can create one or more RRDB files in the RRDB 722 corresponding to the patient monitor 740. The contents of this file or files may depend on the type of patient monitor 740, which may be defined by the patient monitor's 740 serial number, model number, vendor identifier, combinations of the same, or the like. Specific examples of the structure and contents of RRDB files are described in US Patent Publication 2009/0119330, the entire contents of which are hereby incorporated by reference herein.

The RRDB management module **723** can also provide physiological trend data stored in the RRDB to the network management module **721** for transmittal to monitors **740**, nurses' station systems **730**, and/or clinician devices. The RRDB management module **723** may also provide physiological data from the RRDB **722** to the journal management module **725** for purposes described below with respect to FIG. **8**B.

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The journal management module **725**, in certain implementations, receives medical event data from the monitor **740** and the nurses' station system **730** and stores this data in the journal database **724**. In an embodiment, the journal database **724** is a relational database; however, other structures may be used. Each entry of event data may have a corresponding time stamp that indicates when an event occurred. This time stamp may be provided by the journal modules **746** or **736** or by the journal management module **725**. The journal management module **725** may also store event counters in the journal database **724** that reflect a number of times medical events occurred. For example, counters could be stored that count how many alarms occurred within a period of time or how many times a clinician logged on or logged off of a network device.

Advantageously, the journal management module 725 may, in certain embodiments, analyze the medical data in the journal database 724 to determine statistics or metrics of clinician and/or hospital performance. The journal management module 725 may provide an interface to users of the nurses' station system 730 or another computing device to access these statistics. In one example embodiment, journal management module 725 can analyze alarm events and alarm deactivation events to determine clinician response 25 times to alarms. The journal management module 725 may further determine the clinician response times in nurses' day and night shifts. The journal management module 725 may generate reports of these statistics so that hospital administrators, for example, may determine which shifts perform 30 better than others.

More generally, the journal management module **725** may generate reports about clinician and and/or hospital performance by analyzing various statistics derived from data in the journal database **724**. One example of a report is a 35 monitoring report card, which grades a given hospital against other hospitals (or nurses' station against nurses' station, and the like) based at least partly on the derived statistics. Advantageously, hospital administrators, clinicians, and the like may use these statistics and reports to 40 improve the clinician and hospital performance.

Some or all of the features of the clinical network environment 700 may be adapted in certain embodiments. For instance, either or both of the journal modules 746 or 736 may perform some or all of the functions of the journal 45 management module 725. Likewise, one or more journal databases 724 may be stored at the patient monitor 740 and/or nurses' work station 730. Similarly, the RRDB module 724 may perform some or all of the functions of the RRDB management module 723, and an RRDB 722 may be 50 stored at the patient monitor 740. In addition, in some implementations, the clinician devices 650 of FIG. 6 may have RRDB and/or journal modules as well. Many other adaptations, configurations, and combinations may be made in other embodiments. Additional information regarding 55 embodiments of the RRDM can be found in US Patent Publication 2009/0119330.

FIG. 8A illustrates an embodiment of a process 800A for journaling medical events in a journal database. In one embodiment, the process 800A may be implemented by any 60 of the MMS's described above (e.g., the MMS 620 or 720). In particular, the process 800A may be implemented by the journal management module 725. Alternatively, at least some of the blocks may be implemented by the journal modules 736, 746. Advantageously, in certain embodiments, 65 the process 800A facilitates the generation of reports based on the journaled data.

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At block **802**, medical events are journaled in a journal database. In response to requests for report from a user (e.g., a clinician), at block **804** statistics about the medical events are obtained from the journal database. The statistics may include the type, frequency, and duration of medical events, the identity of clinicians or patients associated with the events, alarm response times, combinations of the same, and the like

A report is generated at block **806** regarding the medical event statistics. At block **808**, the report is used to identify potential areas of improvement in hospital operations. For example, the report can be a "monitoring report card" that assigns scores to the hospital or clinicians of the hospital based on their performance.

FIG. 8B illustrates an embodiment of a process 800B for correlating data from a journal database and an RRDB. In one embodiment, the process 800B may be implemented by any of the MMS's described above (e.g., the MMS 620 or 720). In particular, the process 800B may be implemented by the RRDB module 723 and journal management module 725. Alternatively, at least some of the blocks may be implemented by the RRDB module 744 and journal modules 736, 746. Advantageously, in certain embodiments, the process 800B enables physiological information from the RRDB and medical events to be correlated in time. Such a reconstruction of events and physiological data can be akin to aviation "black box" technology, allowing the user to replay clinical actions leading up to medical incidents.

At block **812**, the request is received from a user to review journaled and physiological data corresponding to a period of time. The user may be a clinician, hospital administrator, or the like, who wishes to determine the cause of a problem in the healthcare of a patient. For instance, the user may wish to determine why clinicians failed to respond when a patient's SpO₂ dropped below safe levels.

At block **814**, journaled data is retrieved for the specified period of time from a journal database. This block may be performed by the journal management module **725**. At block **816**, physiological data for the specified period of time is retrieved from an RRDB. This block may be performed by the RRDB management module **723**. The journal data is correlated with the physiological data with respect to time at block **818**. This correlation may include reconstructing a timeline of medical events, with values of physiological parameters (optionally including waveforms) provided in the correct time sequence on the timeline. In some embodiments, to facilitate this coordination between the RRDB management module **723** and the journal management module **725**, timestamps in each database **722**, **724** may be synchronized when the data is stored.

The correlated data is output for presentation to the user at block 820. The output may include, for example, a graphical view of medical events superimposed on physiological information (e.g., a waveform), or the like. Many display formats may be used for the correlated data.

FIG. 9 illustrates an example graphical user interface (GUI) 900 for monitoring patients. The GUI 900 can be provided on a nurses' station system or the like. The GUI 900 can also be displayed on a clinician device.

The GUI 900 includes several display areas. In the depicted embodiment, the GUI 900 includes a patient status display area 910. The patient status display area 910 shows the status of multiple patients in a hospital or other clinical location. In an embodiment, patient status display area 910 depicts patient status for patients in a hospital department.

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Advantageously, in certain embodiments, the patient status display area 910 provides an "at-a-glance" view of multiple patients' health status.

The patient status display area 910 includes a plurality of patient status modules 912. Each patient status module 912 5 can correspond to a patient monitor that can be coupled to a medical patient. Each patient status module 912 can display a graphical status indicator 914. An example graphical status indicator 914 is shown in the screens 900 as a miniature patient monitor icon. The graphical status indicator 914 can selectively indicate one of several states of a patient monitor. In one embodiment, four possible patient monitor states can be depicted by the graphical status indicator 914. These include an alarm condition, a no alarm condition, patient context information status, and connection 15

In various implementations, the graphical status indicator 914 changes color, shape, or the like to indicate one of the different patient monitor states. For example, if an alarm turn red to signify the alarm. If there is no context information available for the patient (see FIG. 1), then the graphical status indicator 914 could turn yellow. If the device is not connected to the patient or the network, then the graphical status indicator 914 could turn gray. And if 25 there is no alarm condition, if there is context information, and if the patient monitor is connected to the patient and the network, then the graphical status indicator 914 could turn green. Many other colors, symbols, and/or shapes could be used in place of or in combination with the above-described 30 embodiments.

Advantageously, the graphical status indicator **914** shows at a glance the status of a patient monitor. Thus, in the patient status display area 910, several graphical status indicators 914 corresponding to several patients show an at-a-glance 35 view for the patient monitors corresponding to these patients. A clinician can therefore readily see the needs that a patient might have with regards to alarms, connection status, and context information.

Currently available graphical user interfaces for nurses' 40 station computers tend to show a plurality of wave forms or changing physiological parameter numbers for each patient. This method of displaying patient information can be cluttered, confusing, and even hypnotic in some situations. Nurses working on a night shift, for instance, may find it 45 difficult to concentrate on an alarm when several other patients' indicators on the display have changing numbers, changing waveforms, or the like. In contrast, in the graphical interface herein described, when the graphical status indicator 914 indicates an alarm condition, this alarm condition 50 can stand out and be immediately recognized by the clinician.

Moreover, the graphical status indicator 914 simplifies the first level of analysis that nurses tend to perform. In currently available devices, nurses often have to analyze wave- 55 forms at the nurses' station to determine the health status of a patient. However, using the screens 900, a nurse need not interpret any waveforms or changing parameters of the patient, but instead can rely on the graphical status indicator 914 that indicates the presence of an alarm.

In certain embodiments, the patient status modules 912 can be selected by a single mouse click or the like. Selecting a patient status module 912 in one embodiment can bring up a patient monitor view area 920. The patient monitor view area 920 shows a view of a patient monitor corresponding to 65 a selected patient status module 912. In certain implementations, the patient monitor view area 920 can show a view

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of the screen from the actual patient monitor device at the bedside of the patient. Thus, a clinician can readily recognize the physiological parameters of the patient in a format that the clinician is likely familiar with. The patient monitor view area 920 is currently receiving physiological information from a patient.

A history view area 930 in certain implementations can show medical event data corresponding to a selected patient monitor status module 912. This medical event data can be obtained from a journal database for inclusion in the GUI 900. The historical view 930 can show, for example, when a sensor was connected or disconnected from a patient, when alarms were active, and when a patient was admitted to the hospital or department. Although not shown, the history view area 930 can also be configured to show trend data obtained from an RRDB instead of, or in addition to, the journaled data.

Transmission of Patient Information to Remote Devices

In some embodiments, the patient monitoring devices condition is present, the graphical status indicator 914 could 20 described herein are capable of transmitting patient information to one or more remote devices for review by a clinician. For example, such remote devices can include remote computers, smart phones, PDAs, etc. This is useful because it enhances the ability of a clinician to monitor a patient's condition remotely. For example, the clinician need not be at the patient's bedside or even at a hospital or other patient care facility in order to effectively monitor the patient's condition.

> In some embodiments, any of the information collected by a patient monitoring device (e.g., the patient monitoring devices described herein) can be transmitted to a remote device. Such information can include, for example, values, trend data, etc. for a medical parameter (e.g., blood oxygen saturation, pulse rate, respiration rate, etc.). It can also include video of the patient and/or audio from the patient and/or the patient's room. For example, video cameras and/or microphones can be provided in the patient's room. In some embodiments, a video camera and/or microphone is incorporated with, for example, a medical monitoring device, such as those described herein. The video camera can image the patient using visible light when the ambient light in the patient's room is of sufficient intensity. The video camera can also be capable of detecting, for example, infrared light when the patient's room is too dark to provide video of acceptable quality using visible light. The video camera can also include an infrared illumination source to illuminate the patient and/or his or her surroundings. In some embodiments, the video camera includes an ambient light sensor that can be used to automatically switch the video camera into infrared mode when the ambient light falls below some threshold. The light sensor can also be used for switching on an infrared illumination source if one is included.

The transmission of patient information (e.g., medical parameter data, video/audio of the patient, etc.) can be made using, for example, one or more communication networks (e.g., computer networks such as LANs, WLANs, the Internet, etc., telephone networks, etc.). In some embodiments, one or more communication networks that are entirely or 60 partially physically located in a hospital or other patient care center can be used. In some embodiments, external communication networks can be used to reach remote devices throughout the world. Thus, clinicians can remotely obtain a vast amount of information regarding the condition of their patients regardless of the clinician's location. In some embodiments, the clinician may also have the capability to directly communicate with the patient. For example, a

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patient monitoring device could include a speaker for broadcasting audio from the clinician's remote device to the patient. Similarly, a patient monitoring device could include a display for showing video from the clinician's remote device (e.g., video teleconferencing). In this way, the 5 exchange of information can be bidirectional to allow the clinician to directly interact with the patient.

Hospital Systems with Location Awareness of Devices and Clinicians

Advanced monitoring systems are capable of displaying 10 many different physiological parameters in many different formats. One possible drawback to this substantial performance capability and display flexibility is that excessive information may be presented to the caregivers that use these systems. These caregivers may include physicians, 15 respiratory therapists, registered nurses, and other clinicians whose uses of the monitoring systems may vary from the taking of routine vital signs to the diagnosis and treatment of complex physiological conditions to clinical research and data collection.

Patient monitoring devices, such as those described herein, may include a keyboard, touchscreen, or other input device to allow a clinician to interact with the device. Such user interface devices can be used to allow a clinician to input login information, such as, for example a username 25 and password. In some cases, a monitoring device may require a clinician to login to the device, for example, before permitting access to one or more of the functions offered by the device, and/or before permitting access to certain information available at the device. The nurses' station, or central 30 monitoring station, as described herein, is an example of one such monitoring device that may require a clinician to login in order to use it. Bedside patient monitors may require a clinician to login before initializing monitoring of a new patient. Even where a clinician is not required to login to a 35 patient monitoring device before using it, the device may still require some type of interaction with an input device in order to cause it to take a particular action from amongst a set of available actions offered by the patient monitoring

For example, user input may be required in order to configure a patient monitoring device in a desired manner. In some embodiments, a clinician may use an input device to change the content offered on the display of the patient monitor device, or the formatting of the content, to suit his 45 or her preferences. In some instances, a nurse may use the input device to manually configure the central monitoring station to display only monitoring information for those patients that are assigned to that particular nurse rather than displaying, for example, all the patients on the entire floor. 50 A clinician may also use an input device to alter patient monitoring settings such as, for example, options for calculating physiological parameter values from raw data, alarm types, physiological parameter alarm limits (e.g., alarm thresholds), etc.

Given the time demands placed on clinicians in busy hospitals, this process of manually interacting with a patient monitoring device by, for example, physically manipulating an input device can be burdensome, especially when it may need to be repeated over and over throughout the day. In 60 some cases, the time required to manually interact with a patient monitor device in order to access a particular function or configure the device can even jeopardize a patient's well-being in particularly urgent circumstances. For at least the foregoing reasons, it would be advantageous for hospital 65 equipment, such as bedside patient monitors, central monitoring stations, and other devices, to have the capability to

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automatically detect the presence of a clinician, and to, for example, take some predetermined action based on the identity of the clinician whose presence is detected.

In some embodiments, a proximity display monitor advantageously adapts an advanced monitoring system to various user needs and preferences by adapting the display to the current observer according to, for example, preference, priority, or user acknowledgement. Accordingly, displayed parameters and formats may be chosen by default according to a predefined user class or customized for particular individuals or groups of individuals. One method of identifying persons in the vicinity of a proximity display is by an ID tag or other token. The ID tag may communicate the user to the proximity display monitor via radio-frequency identification (RFID) or wireless radio transmission as examples. If multiple users are in range of a proximity display monitor, a priority scheme or a user acknowledgment may be used to determine which users are accommo-

In some embodiments, a proximity display monitor has a monitor and an interconnected sensor, the sensor transmits optical radiation into a tissue site and generates a sensor signal responsive to the optical radiation after attenuation by pulsatile blood flow within the tissue site. The monitor may compute physiological parameters responsive to the sensor signal and utilize a proximity display to show the physiological parameters on screen according to a display preference associated with a user in proximity to the monitor. A display can be incorporated with the monitor so as to present the physiological parameters for viewing by a caregiver. A transceiver can be incorporated with the monitor and may be responsive to an identification signal. The identification signal can correspond to a caregiver. A transmitter carried by the caregiver can send the identification signal over a range, for example, approximating the distance from the monitor that a person can reasonably view the display. A preferred screen can present the physiological parameters on the display according to the display preference associated with the caregiver as indicated by the identification signal.

In some embodiments, a proximity display monitor comprises a monitor having a display and a wireless transceiver. The wireless transceiver can be responsive to identification signals which indicate the proximity to the monitor of any users, who have corresponding display preferences. Preferred screens may present the physiological parameters on the display according to the display preferences.

In some embodiments, a proximity display monitor has an optical sensor attached to a fleshy tissue site. A sensor signal may be responsive to optical radiation transmitted by the sensor and detected by the sensor after absorption by pulsatile blood flow within the tissue site. The sensor signal can be communicated to a monitor, which processes the sensor signal so as to derive physiological parameters responsive to constituents of the pulsatile blood flow. The identity of a user in proximity to the monitor can be wirelessly signaled to the monitor. A screen preference, for example, can be determined from the user identity and used to display the physiological parameters on a monitor display.

In some embodiments, a proximity display monitor comprises a processor and a display. The processor can be responsive to a sensor signal generated from optical radiation transmitted into a fleshy tissue site and detected after attenuation by pulsatile blood flow within the tissue site. The processor can be configured to calculate a plurality of physiological parameters indicative of constituents of the pulsatile blood flow. The display may provide a visual representation of the physiological parameters values for

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viewing by proximate users. A wireless communications means can determine the identities of proximate users. Screen preference means may present the physiological parameters on the display. A lookup table means can relate the user identities to the screen preferences.

FIG. 10 illustrates a physiological measurement system having a noninvasive sensor 1010 attached to a tissue site 1000, a patient monitor 1020, and an interface cable 1030 interconnecting the monitor 1020 and the sensor 1010. The physiological monitoring system may incorporate pulse oximetry in addition to advanced features, such as a multiple wavelength sensor and advanced processes for determining physiological parameters other than or in addition to those of pulse oximetry, such as carboxyhemoglobin, methemoglobin and total hemoglobin, as a few examples. The patient monitor 1020 has a proximity display 1021 that presents measurements of selected physiological parameters and that also provides visual and audible alarm mechanisms that alert a caregiver when these parameters are outside of predeter- 20 mined limits. The patient monitor 1020 also has keys 1022 for controlling display and alarms functions, among other items. The proximity display 1021 and keys 1022 provide a user interface that organizes many parameters so that a caregiver can readily ascertain patient status using, for 25 example, a portable, handheld device.

FIG. 11 illustrates various screens 1150 for a proximity display 1021 (FIG. 10) advantageously configured to respond to the presence of a particular user 1130 and to that user's display preference. Users may be any of various 30 caregivers such as treating physicians or attending nurses. In an embodiment, the proximity display 1021 (FIG. 10) may also respond to any of a particular group of users.

As described with respect to FIG. 13, below, the presence or proximity of a particular user or group of users to the 35 monitor 1020 (FIG. 10) may be determined by a user wearing an RFID (radio frequency identification) tag or other wireless communications. Then, a particular screen or screens can be presented on the display according to a predetermined display preference associated with the user. 40 In this manner, a proximity display 1021 (FIG. 10) is tailored to the preferences of monitor users. An "RFID tag" or simply "tag" can include any wireless communication device that can remotely identify a proximate user to a monitor. Tags include, but are not limited to, devices in the 45 form of badges, tags, clip-ons, bracelets or pens that house an RFID chip or other wireless communication components. Tags also encompass smart phones, PDAs, pocket PCs and other mobile computing devices having wireless communications capability.

As shown in FIG. 11, by example, an anesthesiologist 1131 proximate the monitor is identified and the display is changed to a screen 1110 showing pulse rate trend. When a nurse 1132 is proximate the monitor, the display is changed to a screen 1120 showing pulse oximetry parameters, a 55 plethysmograph and alarm limits. When a respiratory therapist 1133 is proximate the monitor, the display is changed to a screen 1140 showing pulse oximetry, abnormal hemoglobin and perfusion indices.

In some embodiments, a proximity display monitor 60 responds to the departure of all proximate users by automatically dimming the display to a reduced brightness setting. This feature advantageously avoids disturbance of a patient who is sleeping or attempting to sleep. In some embodiments, a proximity display monitor responds in a 65 similar manner by automatically silencing pulse "beeps" and other non-critical sounds when there are no proximate users.

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FIG. 12 illustrates a proximity display monitor 1200 that responds to a nearby user 1280 so as to display calculated parameters according to a user display preference. As shown in FIG. 12, the proximity display monitor 1200, in some embodiments, has a front-end 1210 that interfaces with an optical sensor (not shown). The optical sensor generates a sensor signal responsive to pulsatile blood flow with a patient tissue site. An optical sensor is described in U.S. patent application Ser. No. 11/367,013 titled Multiple Wavelength Sensor Emitters, cited above. The front-end 1210 conditions and digitizes the sensor signal 1212, which is input to a digital signal processor (DSP) 1220. The DSP 1220 derives physiological parameters 1222 according to the sensor signal 1212. The calculated parameter values are communicated to a display driver 1230, which presents the parameters on the display 1270 according to a predetermined format. A monitor having a front-end and DSP is described in U.S. patent application Ser. No. 11/366,208 titled Noninvasive Multi-Parameter Patient Monitor, cited

Also shown in FIG. 12, the proximity display monitor 1200 has a transceiver or receiver 1240, a lookup table 1250 and display preferences 1258. The user 1280 has an ID tag 1260 that identifies the user 1280 to the transceiver 1240. When the user 1280 is in the vicinity of the proximity display monitor 1200, the ID tag 1260 is able to communicate with the transceiver 1240 so as to identify the user 1280. In an embodiment, the transceiver 1240 is an RFID reader and the ID tag 1260 has an embedded RFID chip containing a user code 1252. In another embodiment, the transceiver 1240 complies with one or more short-range wireless communications standards, such as Bluetooth®. The user 1280 can initiate communications with the proximity display monitor 1200 by, for example, pressing a button or similar initiator on the ID tag 1260, and a user code 1252 is transmitted to the transceiver 1240. The transceiver 1240 communicates the user code 1252 to the DSP 1220. The DSP can access the lookup table 1250 so as to derive a display preference 1258 from the received user code 1252. The display preference 1258 indicates the display parameters 1222 and screen format 1224, which are communicated to the display driver 1230.

Further shown in FIG. 12, in some embodiments, the lookup table 1250 relates the user code 1252 to a caregiver ID 1256 and a priority 1254. When multiple users are in the vicinity of the proximity display monitor 1200, the priority 1254 determines which display preference 1258 is used to configure the display 1270.

FIG. 13 illustrates a display preference screen 1300, which provides information for a particular row of the look-up table 1250 (FIG. 12). A setup or registration procedure allows users to specify one or more profiles including, for example, a display preference and various options for calculating parameters and triggering alarms.

FIG. 14 is a schematic diagram of a patient monitoring device 1400 that is capable of automatically detecting the presence of a clinician token 1410. In some embodiments, the clinician token 1410 is a portable item meant to be, for example, worn or carried by a clinician throughout the day. The patient monitoring device 1400 is able to recognize the presence of the clinician based upon the presence of that clinician's token.

The patient monitoring device 1400 includes a detector such as, for example, a communication module 1402. The patient monitoring device 1400 also includes a display 1404, and a processor 1406. The processor 1406 can be used, for example, for carrying out clinically-useful tasks on the basis

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of physiological information collected from one or more patients (e.g., calculating physiological parameter values, determining alarm conditions, outputting physiological information via a clinician user interface, notifying a clinician of an alarm condition, etc.) The patient monitoring 5 device 1400 can also include other modules to assist in the monitoring of patients, as described herein (e.g., an interface for receiving physiological information from a medical sensor or computer network, a user interface for facilitating interaction with a clinician, etc.). In some embodiments, the 10 communication module 1402 is a transmitter, a receiver, or a transceiver. Other types of communication modules can also be used. In some embodiments, the communication module 1402 is a short-range transceiver. The short range transceiver can be, for example, a Bluetooth-enabled trans- 15 ceiver. Bluetooth is a wireless protocol for exchanging data between devices over relatively short distances. The communication module 1402 can also be an infrared transceiver, an RFID tag, or any other means of communication (e.g., short-range communication).

The communication module **1402** is capable, in some embodiments, of detecting signals from a remote device within a detection area **1420**. The size of the detection area of **1420** can be determined by, for example, the power levels of communication signals from the communication module 25 **1402**. The size of the detection area **1420** may also be affected by the surroundings of the patient monitoring device **1400**. In some embodiments, the detection area **1420** is configured to have a radius of 30 feet or less. In some embodiments, the radius is 10 feet or less, while in some embodiments, the radius is 5 feet or less, or 3 feet or less.

The clinician token 1410 can likewise include a communication module 1412, which can be, for example, a trans- 35 mitter, a receiver, or a transceiver, though other types of communication modules may also be used. As is the case with the patient monitoring device 1400, the communication module 1412 included with the clinician token 1410 may be a short range transceiver, such as, for example, a Bluetooth 40 transceiver. The patient monitoring device 1400 is capable of detecting the presence of a clinician based on, for example, recognition of one or more communication signals from a clinician token 1410. A communication signal from the clinician token 1410 may come, for example, in response 45 to a communication initiated by the patient monitoring device 1400, or the communication signal from the clinician token 1410 may be initiated by the clinician token itself. Many different methods can be used for initiating, for example, wireless communication between remote devices. 50

The clinician token 1410 may also carry information, for example, in a memory. The memory may be, for example, volatile or nonvolatile memory. The information may be hardwired into the clinician token 1410 or programmable. In some embodiments, the clinician token 1410 includes a clinician ID 1414 that is unique to the clinician to whom the clinician token 1410 is assigned. The clinician token 1410 may also include other information such as, for example, a clinician's login information (e.g., user name and password), a code or other indicator for initiating a predetermined 60 action to be performed by the patient monitoring device 1400 upon recognition of the clinician's presence (logging in the clinician, setting configuration preferences of the patient monitoring device 1400, enabling a function, etc.).

The clinician token **1410** may also include an input 65 module **1416** that allows the clinician to cause the communication module **1412** to remotely communicate with, for

example, the patient monitoring device 1400, or some other device that forms a part of the hospital's patient monitoring network. For example, the input module 1416 may include one or more buttons, or other input devices, that allow the clinician to initiate a communication with the patient monitoring device 1400 for the purpose of having that device recognize the clinician's presence. In addition, the clinician may use the input module 1416 to, for example, call in an appropriate recognize the clinician if the clinician discovery that a

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emergency response team if the clinician discovers that a particular patient is in need of emergency attention, or to silence a monitoring alarm. The input module **1416** can also be used for other purposes, depending upon the application.

In some embodiments, the clinician token 1410 is a cell phone, notebook computer, PDA device, headset, etc., any one of which may be, for example, Bluetooth-enabled. In some embodiments, the clinician token 1410 is the pager, or other notification device, used to notify clinicians of physiological parameter alarm conditions, as described herein. In some embodiments, the clinician token 1410 is an active or passive RFID tag. An active RFID tag may be WiFi-enabled. for example. In some embodiments, the clinician token 1410 is a barcode (e.g., two-dimensional or three-dimensional). In some embodiments, the clinician token 1410 is a part of the clinician's body. For example, the clinician token 1410 may be a fingerprint, a retina, the clinician's face, etc. In such embodiments, the clinician ID 1414 is actually a unique biometric signature of the clinician. The communication module 1402 may be selected based upon the type of clinician token 1410 with which it is to communicate. For example, the communication module 1402 in the patient monitoring device 1400 may be an RFID interrogator, a barcode scanner, a fingerprint scanner, a retina scanner, a facial recognition device, etc.

In some embodiments, the clinician token 1410 is advantageously a consumer device that can be registered with the patient monitoring device 1400 but that has no prior connection or relationship with, for example, the patient monitoring device 1400, a patient monitoring system, the hospital, etc. For example, the clinician token 1410 can be a consumer device that is not designed specifically for the purpose of communicating with the patient monitoring device 1400, or any other device configured to be able to detect the presence of the clinician token. Many clinicians will already own, for example, a cell phone which is carried on the clinician's person throughout the day for the clinician's personal use. In some embodiments, the clinician's personal electronic device can function as the clinician token 1414, for example, after a registration process that will be described herein. This can be advantageous because it does not require investment on the part of the hospital or other caregiver facility to provide each clinician with a specialpurpose clinician token 1410. Nevertheless, in some embodiments, the clinician token 1410 is a special-purpose device provided to the clinician for the primary purpose of operating with, for example, patient monitoring devices (e.g., 1400) having presence detection functionality.

In some embodiments, the clinician token 1410 is capable of responding to, for example, interrogation from a patient monitoring device only with a fixed response signal (e.g., a clinician ID 1414). In some embodiments, however, the clinician token 1410 is capable of transmitting multiple, and/or variable, signals and information to the patient monitoring device 1400. The clinician token 1410 may include a processor capable of executing, for example, software applications that allow the clinician token 1410 the capability of a variety of intelligent communications with the patient monitoring device 1400.

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In some embodiments, a registration process is completed before the clinician token 1410 is used with the patient monitoring device 1400 to implement presence detection functionality. For example, during a registration process, the clinician token 1410 may be endowed with a unique clinician ID 1414 assigned to a particular clinician. This clinician ID may be stored in a database that is, for example, accessible by the patient monitoring device 1400 such that the patient monitoring device 1400 can determine the identity of the clinician based upon the clinician ID 1414 stored in the clinician token 1410. The clinician ID 1414 can also be associated in the database with, for example, the clinician's assigned login information for accessing the patient monitoring device 1400.

The database can also store an indication of the action, or 15 actions, that the clinician desires a particular patient monitoring device to take upon detection of the clinician's presence. The database can store the clinician's configuration preferences for the patient monitoring device. For example, the particular physiological parameters and other 20 monitoring information that are shown on the display 1404 of the patient monitoring device 1400 may be configurable. In the case of bedside patient monitors, for example, the display 1404 may be capable of showing numerical indicators of a particular physiological parameter, graphical indi- 25 cators of the physiological parameter, visual alarms, multiple physiological parameters simultaneously, signal quality of physiological parameter signals from a patient sensor, etc. The clinician's configuration preferences can indicate to the monitoring device 1400 what type of information to display 30 and how to format the displayed information. The clinician's configuration preferences for the patient monitoring device 1400 can also include patient monitoring settings such as, for example, physiological parameter alarm limits.

In the case of, for example, a central monitoring station, 35 such as the type described herein, the clinician's configuration preferences may likewise include the type and display format of a physiological parameter, or other monitoring information, that is shown for each of the patients being monitored at the central monitoring station. In addition, the 40 clinician's configuration preferences can include a fixed or dynamic list of patient rooms, or patient names, to be displayed at the central monitoring station. These rooms, or patients, can be those currently assigned to that particular clinician, for example. In general, however, the clinician's 45 configuration preferences that are associated with the clinician ID 1414 can include any configurable feature, aspect, or function of the patient monitoring device 1400.

The database can associate with the clinician ID **1414** a particular action that the clinician may wish to initiate upon 50 entering the detection area **1420** of the patient monitoring device **1400**. Examples of such actions that can be initiated automatically upon detection of the clinician's presence are described herein. In addition, in some embodiments, the database can also associate with the clinician ID **1414** a 55 priority level. The priority level can indicate which clinician should be given priority access to a medical monitoring device **1400**, for example, when multiple clinicians are detected in the detection area **1420** simultaneously.

In some embodiments, the clinician's assigned login 60 information, monitoring device configuration preferences, list of actions to automatically initiate upon recognition of the clinician's presence, priority level, and/or other information can be stored by the clinician token 1410 itself. In such embodiments, this information may be transmitted 65 directly to the patient monitoring device 1400 by the clinician token 1410 as opposed to the patient monitoring device

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1400 obtaining the information from a database using the clinician ID 1414 stored on the token 1410. Other methods can also be used in order to associate, for example, a clinician ID 1414 with a predetermined action (e.g., logging in, configuration change, etc.) that the clinician wishes the patient monitoring device 1400 to take or assume when the clinician is in the detection area 1420 of the device 1400.

In some embodiments, once a registration process is complete, the patient monitoring device 1400 is capable of detecting the presence of a particular clinician based upon the clinician's token 1410, and of taking, for example, a clinician-specific action based upon recognition of the clinician's presence. In some embodiments, the processor 1406 of the patient monitoring device 1400 is configured to execute detection logic 1408 for determining when a clinician token 1410 is or is not present in the detection area 1420 of the monitoring device 1400. In some embodiments, the detection logic 1408 is a set of rules or other criteria that must be satisfied before a clinician token 1410 is determined to be present in the detection region 1420, or before some clinician-specific action is performed.

FIG. 15 is a flowchart illustrating detection method 1500 for detecting the presence of a clinician token (e.g., 1410) within the detection region of a patient monitoring device. The detection method 1500 can begin, for example, at a waiting state 1502 where the patient monitoring device 1400 has not detected the presence of a clinician. In the waiting state 1502, the patient monitoring device 1400 can allow manual access, for example, to the features and information that can be provided by the device 1400. In the waiting state 1502, the patient monitoring device can also allow manual configuration of the device, or interaction with the device, by a clinician using an input device such as a keyboard, mouse, or touchscreen. Thus, the waiting state 1502 advantageously allows clinicians who may not have an assigned clinician token 1410 to nevertheless use and interact with the patient monitoring device 1400.

At decision block 1504, the processor 1406 executes the detection logic 1408 to determine whether a signal is detected from a clinician token 1410. For example, in some embodiments, the communication module 1402 of the patient monitoring device 1400 may, for example, continuously, or periodically, transmit a clinician token discovery signal. At decision block 1504, the processor 1406 can determine whether a response has been received from a clinician token 1410 to the patient monitoring device's discovery signal. Alternatively, or additionally, the clinician token 1410 can be configured to, for example, continuously, or periodically, transmit a discovery signal which the patient monitoring device 1400 can detect. Response signals from the clinician token 1410 can include, for example, the clinician ID 1414 or other information. If no signal is detected from a clinician token 1410, then the detection method 1500 returns to the waiting state 1502. If, however, a signal from a clinician token 1410 is detected, then the detection method 1500 can proceed to the next decision

At decision block 1506, the processor 1406 executes the detection logic 1408 to determine whether the detected signal from the clinician token 1410 exceeds a signal strength threshold value. This test can be useful, for example, as an estimate of the physical distance between the clinician token 1410 and the patient monitoring device 1400. For example, the patient monitoring device 1400 may be configured such that whether or not a detection event occurs, and/or the particular predetermined action it takes upon detection of a clinician, is dependent upon the estimate of

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the physical distance between the clinician and the patient monitoring device 1400. This may be useful, for example, in the case of a central monitoring station that is near a high traffic area where many clinicians regularly pass by. In such situations it may be advantageous to set the signal strength 5 threshold used in decision block 1506 at a relatively high level so as to limit the clinician detection events to situations where a clinician is a relatively small distance away from the central monitoring station. Thus, the signal strength threshold can be configurable based, for example, upon a desired 10 physical distance from a clinician token 1410 before recognizing a clinician presence detection event. If the signal strength of the signal detected from a clinician token 1410 is below the signal strength threshold used by the decision block 1506, then the detection method 1500 returns to the 15 waiting state 1502. If, however, the signal strength exceeds the threshold, then the detection method 1500 can proceed to the next decision block 1508.

At decision block 1508, the processor 1406 executes the detection logic 1408 to determine whether the signal 20 strength of the signal from the clinician token 1410 has exceeded the signal strength threshold for a proximity time that is greater than a time threshold. This test can be useful to avoid recognizing a clinician presence detection event in cases where a clinician passes nearby the patient monitoring 25 device 1400 but does so only transiently, not remaining within the detection region 1420 for a long enough period of time to merit a clinician presence detection event. This test can likewise help eliminate false clinician presence detection events in high-traffic areas around a patient monitoring 30 device 1400 where many different clinicians routinely and regularly pass by. The proximity time threshold used by the decision block 1508 can be configurable. In some embodiments, the proximity time threshold may be set at, for example, 1 second, 2 seconds, or 5 seconds. Other proximity 35 times can also be used, however. If the proximity time for a detected clinician token 1410 does not exceed the proximity time threshold used by decision block 1508, then the detection method 1500 returns to, for example, the waiting state **1502**. If, however, the proximity time of the clinician token 40 **1410** exceeds the proximity time threshold, then the detection method 1500 can proceed to block 1510.

At block 1510, a clinician presence detection event is recognized. At such time, the patient monitoring device 1400 can enable or initiate, for example, some predeter- 45 mined action based upon the clinician identity associated with the recognized clinician token 1410. For example, the patient monitoring device 1400 can login the clinician, change a configuration setting, authorize some action or feature that is typically restricted absent the presence of a 50 clinician, etc. In the detection method 1500 illustrated in FIG. 15, whether or not a clinician presence detection event occurs is dependent upon the signal strength of a signal from the clinician token 1410 as well as the length of time that the signal from the clinician token 1410 exceeds a signal 55 strength threshold. In some embodiments, however, a clinician presence detection event can be recognized based only on signal strength from the clinician token 1410, or based only on the length of time that a signal is detected from a clinician token 1410.

In some embodiments, other factors can be included in the detection logic 1408, whether alone or in combination with signal strength from the clinician token 1410 and proximity time. For example, the recognition of a clinician presence detection event can be based, at least in part, on the identity 65 of the clinician (some patient monitoring devices 1400 may only be accessible to certain clinicians). In addition, the

recognition of a clinician presence detection event can be based upon the assigned priority of the clinician. For example, a nurse supervisor could be assigned a higher priority than other nurses on the shift such that the presence of the nurse supervisor will be recognized by a patient monitoring device 1400 even when the presence of another nurse has already been recognized by the device. The converse situation, however, may not result in a new clinician presence detection event; the detection of a lower priority clinician may not result in a detection event if the presence of a higher priority clinician has already been recognized by the patient monitoring device 1400. The priority level is one example of a tiebreaker criteria that can be used by the detection logic 1408 in the event that multiple clinician tokens meet the other requirements to initiate a clinician detection event at the same time. Other criteria can also be used in this tiebreaker role.

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It should be appreciated that a wide variety of factors can be included in the detection logic 1408 depending upon the hospital, the type of medical equipment involved (e.g., patient monitoring equipment or some other type of medical device). In addition, such factors can be accounted for in the detection logic 1408 in a variety of ways. For example, the detection logic 1408 can determine when thresholds are exceeded, when a Boolean expression is true or false, when a fuzzy logic expression is true or false, when a mathematical equation is satisfied or not, when a compound rule is satisfied or not, etc.

When a clinician detection event has been realized according to, for example, the detection method 1500, the patient monitoring device 1400 can respond in a number of different ways. For example, the patient monitoring device 1400 can initiate a predetermined action based upon the identity of the clinician whose token has been detected in proximity to the monitoring device. In some embodiments, the predetermined action is that the patient monitoring device 1400 automatically logs the clinician in without requiring the clinician to, for example, physically interact with an input device. This process saves the clinician time and, in some cases, can also save patient lives. As described herein, the clinician's login information can be transmitted to the patient monitoring device 1400 from the clinician token 1410, or it can be retrieved from a database using the clinician ID 1414 from the token 1410.

In some embodiments, the patient monitoring device enables or disables a particular feature based upon detection of the clinician token 1410. For example, the patient monitoring device may enable/disable menus and buttons (e.g., alarm limit menu, alarm silence, all mute, etc.) based upon the credentials of the detected clinician. In some embodiments, the patient monitoring device 1400 begins transmission of patient monitoring information to a remote device upon detecting the presence of a clinician. For example, a bedside patient monitor capable of capturing breathing sounds from a patient could automatically begin transmission of those breathing sounds to the clinician's Bluetooth headset, which, incidentally, can serve as the clinician token **1410** as well. In other embodiments, the patient monitoring device 1400 could begin transmission of any type of monitoring information to a remote device via, for example, the Internet upon detecting the presence of a particular clinician. For example, the patient monitoring device 1400 can transmit the patient's oxygen saturation trend data to the clinician's computer for later analysis and diagnosis. The patient monitoring device 1400 can also transmit any other type of patient information (e.g., medical parameter values and/or trend data, video and/or audio from the patient's room, etc.)

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to, for example, the clinician's computer, or some other device, in response to detection of the presence of some particular clinician in proximity to the patient monitoring device 1400.

In some embodiments, the patient monitoring device 5 automatically updates its configuration based upon configuration preferences of a detected clinician. For example, the patient monitoring device 1400 could alter the content of the information it displays or the format of the information that it displays. These configuration changes can be made based upon settings that the clinician indicates during the registration process for the clinician token 1410. An example of such an embodiment is illustrated in FIG. 16. In some embodiments, a patient monitoring device changes the layout of a display screen (e.g., the number of parameters 15 shown, the waveforms shown, trends, and other screen controls). Display layouts can be selected from predefined layouts, or a clinician can make a custom layout. The same is true of other configuration settings. Configuration settings can be associated with clinicians at an individual user or 20 group level. A hierarchy of layouts modes can be established for layout conflicts.

The patient monitoring device **1400** can also update other configuration settings based upon registered preferences of the clinician. These can include physiological parameter 25 alarm limits, alarm silence, all mute, averaging time, algorithm mode, etc., for example. In addition, the patient monitoring device **1400** could automatically create some type of report, such as a report of all alarm conditions that have been registered by that monitor over a predetermined 30 period of time.

In addition, alarm annunciation and behavior can be altered in response to a clinician proximity detection event. For example, if the clinician is approaching a bedside patient monitoring device 1400 that is currently registering an alarm 35 condition, the alarm can automatically be silenced in recognition that the clinician has entered within a certain radius of the monitoring device 1400. In some embodiments, the way that the patient monitoring device 1400 notifies of an alarm condition can be dependent upon the physical location 40 of a clinician. For example, if the patient monitoring device 1400 detects an alarm condition while the clinician is already in proximity to the monitoring device, then it may emit no audible alarm or a lower-volume audible alarm. Alarm volume can also be adjusted in other ways based upon 45 detected clinician presence. Similarly, in such a scenario, the patient monitoring device 1400 may be configured not to transmit an alarm to the central monitoring station. In some embodiments, a medical monitoring device does not notify or page other clinicians in case of an alarm if a clinician is 50 already present. Alarm notification behavior of the medical monitoring device can be altered in a variety of ways based upon detected presence of a clinician. A medical monitoring device with clinician proximity awareness can allow a detected clinician to acknowledge his or her presence. As 55 long as clinician presence is detected, the length of expiry of alarms can be changed (e.g., made longer).

In some embodiments, the patient monitoring device 1400 responds to detection of a clinician's presence by changing the language in which textual information is displayed by 60 the monitoring device in accordance with language preferences of the clinician. In some embodiments, the patient monitoring device identifies and executes on-device confirmations that may be required for risk management based upon the detected clinician(s) in proximity to the monitoring 65 device. In some embodiments, the patient monitoring device logs the number of clinician visits to a patient's bedside, the

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time of presence of each visit, the length of each clinician visit, the response time of clinicians to alarms, etc. A clinician may be permitted to chart parameters measured by the monitoring device to, for example, an electronic medical record with credentials based upon detection of clinician identity. Many other types of actions and/or configuration changes, or combinations of those described herein, can also be caused to automatically be initiated based upon the fact that a clinician has been detected in proximity to the patient monitoring device 1400.

FIG. 16 illustrates an example graphical user interface 1600 of nurses' station or central patient monitoring station. The graphical user interface 1600 includes features similar to those described with respect to FIG. 9. For example, the graphical user interface 1600 includes a patient status display area 1610. The patient status display area 1610 includes a plurality of patient status modules 1612, each having a graphical status indicator 1614. The graphical user interface 1600 also includes a patient monitor view area 1620 and a history view area 1630.

As illustrated in FIG. 9, the central patient monitoring station includes several patient status display areas, each showing monitoring information from a different patient. Unlike FIG. 9, however, which shows the status of a number of patients larger than a single nurse could possibly attend to individually, FIG. 16 shows only those patients assigned to a particular clinician. The display of the central patient monitoring station can be automatically updated from that of FIG. 9, for example, to that of FIG. 16 in recognition of the presence of a clinician. In this way, the clinician can quickly and conveniently check the status of each of his or her assigned patients at a glance by simply approaching the central patient monitoring station without having to actually physically interact with a central patient monitoring station. In addition, the proximity detection features described herein can be used to facilitate assignments of clinicians to patients at the nurses' station. For example, patients can be added to the view of FIG. 16 automatically if the clinician has been detected in proximity to the patient's bedside monitor within some predetermined period of time.

FIG. 17 is a flowchart illustrating a method 1700 for determining when to disable a clinician-specific action that had been previously enabled by a patient monitoring device 1400 based upon the detected presence of the clinician. The method 1700 begins at block 1702 where some clinician-specific action has been previously enabled, as described herein. The method 1700 then proceeds to decision block 1704 and decision block 1708. For example, the method 1700 may involve detecting whether a previously-detected clinician remains in proximity to a patient monitoring device while simultaneously detecting whether a higher priority clinician arrives in proximity to the patient monitoring device. For example, the process illustrated by decision block 1708 can generate an interrupt signal if the presence of a higher priority clinician is detected.

At decision block 1704, the processor 1406 executes the detection logic 1408 to determine whether the strength of a signal from the clinician token 1410 has fallen below a signal threshold. This threshold can be the same threshold as used by the decision block 1506 in FIG. 15. Alternatively, these two thresholds can be different to provide a degree of hysteresis in the detection system to guard against the situation where a clinician token 1410 could be recognized as switching between the present and absent states repeatedly in quick succession if the strength of the signal from the clinician token 1410 happens to be approximately equal to the selected threshold value. If the strength of the signal

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from the clinician token 1410 has not fallen below the signal threshold, then the method 1700 returns to block 1702 where the clinician-specific action remains enabled. If, however, the strength of the signal from the clinician token 1410 falls below the threshold used in decision block 1704, then the 5 method 1700 proceeds to decision block 1706.

At decision block 1706, the processor 1406 executes the detection logic 1408 to determine whether the strength of the signal from the clinician token 1410 has fallen below the signal threshold for an absence time that is greater than a 10 time threshold. Thus, the combination of decision blocks 1704 and 1706 determine whether the clinician token has been outside of a particular range for a particular amount of time. In some embodiments, this time threshold can be variable depending upon, for example, the content of information displayed by the medical monitoring device 1400. For example, if the monitoring device 1400 is displaying sensitive personal information, then the time threshold can be relatively short in order to protect the patient's confidentiality.

If the absence time does not exceed the time threshold used by the decision block 1706, then the method 1700 returns to block 1702 where the clinician-specific action remains enabled. If, however, the absence time exceeds the time threshold, then the method 1700 proceeds to block 25 1710. At block 1710, the clinician is recognized as no longer being in proximity to the patient monitoring device 1400. Therefore, the previously-enabled clinician-specific action is disabled. At such time, the patient monitoring device 1400 can return to a state similar to the waiting state 1502 30 described with respect to FIG. 15. In some embodiments, the action performed by the patient monitoring device 1400 at block 1710 can substantially reverse any action taken by the monitoring device at block 1510 in FIG. 15. For example, if the clinician was automatically logged in to the patient 35 monitoring device 1400 when his or her presence was initially detected, then at block 1710, that clinician can be logged out. Similarly, if the configuration of the monitoring device 1400 was changed based upon the detected clinician's preferences, then, at block 1710, those configuration 40 changes can be restored to, for example, a default state.

With reference now to the decision block 1708, the processor 1406 executes the detection logic 1408 to determine whether the presence of a higher priority clinician has been detected. The detection of such a clinician can proceed, 45 for example according to the detection method 1500 described with respect to FIG. 15. As described herein, each clinician can be assigned a priority value that can act as a tiebreaker criteria to determine the presence of which clinician to recognize when more than one clinician is detected. 50 If no higher priority clinician is detected at decision block 1708, then the method 1700 returns to block 1702. If, however, a higher priority clinician is detected at decision block 1708, then the method 1700 may proceed to block 1710 where the recognition of the presence of the previously-detected clinician is revoked, and the presence of the newly detected higher-priority clinician is recognized.

FIG. 18 is a schematic diagram of a system for enabling a patient monitoring device 1800 to automatically detect the presence of a clinician token 1810. The patient monitoring 60 device 1800 and the clinician token 1810 can be similar, for example, to the patient monitoring device 1400 and clinician token 1410 described herein with respect to FIG. 14 except as otherwise indicated. In the embodiment illustrated in FIG. 18, the patient monitoring device 1800 detects the presence 65 of the clinician token 1810 with the assistance of, for example, one or more WiFi access points 1830-1832. The

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WiFi access points 1830-1832 can be advantageously distributed throughout the patient care environment where patient monitoring is occurring. The WiFi access points 1830-1832 can operate based on IEEE 802.11 standards, for example.

The communication module 1802 of the patient monitoring device 1800 can be, for example, a WiFi-enabled radio for communicating with the WiFi access points 1830-1832. In some embodiments, the clinician token 1810 is a WiFienabled RFID tag. By communicating with the WiFi access points 1830-1832, the patient monitoring device 1800 can triangulate its position relative to that WiFi access points. Likewise, the position of the clinician token 1810 can be triangulated. Thus, the distributed WiFi access points 1830-1832 can be used by, for example, the patient monitoring device 1800 in order to determine the approximate position of the clinician token 1810 with respect to the monitoring device 1800. In some embodiments, the patient monitoring device 1800 may also communicating directly with the 20 clinician token **1810** in order to, for example, enhance the position approximation determined using the distributed WiFi access points 1830-1832.

FIG. 19 is a schematic illustration of a patient monitoring device network 1900 having a clinician proximity awareness feature. The patient monitoring device network 1900 can be similar to those shown, for example, in FIGS. 1, 2, 6, and 7. The patient monitoring device network 1900 includes multiple bedside patient monitors 1902, 1912, 1922 for monitoring multiple patients 1906, 1916, 1926. In some embodiments, each of the bedside patient monitors 1902, 1912, 1922 is similar to those shown in, for example, FIG. 14 (1400) and FIG. 18 (1800). The bedside patient monitors 1902, 1912, 1922 are capable of detecting the presence of a clinician based upon the clinician tokens 1904, 1914, 1924. The clinician tokens 1904, 1914, 1924 can be similar, for example, to those shown in FIG. 14 (1410) and FIG. 18 (1810).

The patient monitoring device network 1900 also includes a nurses' station 1932 for remotely monitoring each of the patients 1906, 1916, 1926. The nurses' station, or central monitoring station, 1932 can be similar to those described herein. The patient monitoring device network 1900 may also include a registration database 1942. As described herein, the registration database 1942 can associate unique clinician IDs (e.g., 1414, 1814) carried by the clinician tokens 1904, 1914, 1924, 1934 with information for controlling the patient monitoring devices 1902, 1912, 1922, 1932 when the tokens are in the presence of those devices. For example, the registration database 1942 can associate each unique clinician ID with login information, configuration preferences, and predetermined actions for the monitoring devices to perform after recognizing the presence of a clinician.

block 1708, then the method 1700 may proceed to block 1710 where the recognition of the presence of the previsually-detected clinician is revoked, and the presence of the newly detected higher-priority clinician is recognized.

FIG. 18 is a schematic diagram of a system for enabling a patient monitoring device 1800 to automatically detect the presence of a clinician token 1810. The patient monitoring device the patient monitoring device network 1900, each of the patient monitoring devices 1902, 1912, 1922, 1932 can communicate with one another via the network 1950 uses open source communications standards in order to facilitate communication between various medical devices. Though not illustrated, the patient monitoring device network 1900, each of the patient monitoring device network 1950 uses open source communication between various medical devices. Though not illustrated, the patient monitoring device network 1900, each of the patient monitoring device network 1900, each of the patient monitoring device network 1900, each of the patient monitoring devices 1902, 1912, 1922, 1932 can communicate with one another via the network 1950 uses open illustrated, the patient monitoring device network 1900, each of the patient monitoring devices 1902, 1912, 1922, 1932 can communicate with one another via the network 1950 uses open illustrated, the patient monitoring devices 1902, 1912, 1922, 1932 can communicate with one another via the network 1950 uses open illustrated, the patient monitoring device network 1900, each of the patient monitoring devices 1902, 1912, 1922, 1932 can communicate with one another via the network 1950 uses open illustrated patient monitoring devices 1902, 1912, 1922, 1932 can communicate with one another via the network 1950 uses open illustrated, the patient monitoring device network 1900 can device 1800 and the clinician token 1810 can be similar, for each of the patient monitoring devices 1902, and of the patient monitoring devices 1903 and the clinician token 1810 can be similar, for e

FIG. 20 is a schematic drawing of a hospital floor 2000 with distributed WiFi access points 2030-2034 that can be used to estimate the physical locations of medical devices 2002, 2004, patients 2010, 2012, and clinicians 2014, 2016. The WiFi access points 2030-2034, or other detectors, can

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be distributed throughout the hospital floor, or other physical region, in order to provide WiFi coverage throughout the patient care area. In some embodiments, the WiFi access points 2030-2034 have respective coverage areas 2040-2044 that the overlap one another. In some embodiments, the WiFi access points 2030-2034 are populated densely enough so that at least three coverage areas 2040-2044 of the WiFi access points 2030-2034 overlap in substantially every portion of the hospital floor in which it is desired to track the positions of medical devices 2002, 2004, patients 2010, 10 2012, and clinicians 2014, 2016. The access points 2030-2034 can be mounted, for example, on or in walls, on or in ceilings, etc.

The medical devices 2002, 2004 can be similar to others described herein. For example, in some embodiments, the 15 medical devices 2002, 2004 are patient monitoring devices. In some embodiments, the medical devices 2002, 2004 are fitted with tracking tags or tokens 2006, 2008. The tracking tags 2006, 2008 can be similar to the clinician tokens described herein. In some embodiments, the tracking tags 2006, 2008 are WiFi-enabled RFID tags, though other types of tracking tags may also be suitable. Each tracking tag 2006, 2008 can include an equipment ID.

As already discussed herein, the clinicians 2014, 2016 may carry clinician tokens 2022, 2024. The clinician tokens 25 2022, 2024 can be similar to those described herein. For example, in some embodiments, the clinician tokens 2014, 2016 are WiFi-enabled RFID tags. In some embodiments, each patient 2010, 2012 may also be fitted with a patient token 2018, 2020. The patient tokens 2018, 2020 can be 30 similar to the clinician tokens described herein. In some embodiments, the patient tokens 2018, 2020 are WiFienabled RFID tags. These may be worn as bracelets, or otherwise suitably affixed to the patients. Each patient token 2018, 2020 can include a patient ID.

The distributed network of WiFi access points 2030-2034 can be used to communicate with the medical device tracking tags 2006, 2008, the clinician tokens 2022, 2024, and the patient tokens 2018, 2020 for the purpose of estimating the physical position of each of these tags and tokens in the 40 hospital 2000. For example, the WiFi access points 2030-2034 can be used to triangulate the position of each tag or token.

While FIG. 20 illustrates a distributed network of WiFi access points 2030-2034 that can be used for detecting the 45 positions of the tracking tags 2006, 2008, the clinician tokens 2022, 2024, and the patient tokens 2018, 2020, other devices can also be used for similar purposes. For example, in some embodiments, the WiFi access points 2030-2034 are eliminated and medical devices 2002, 2004 with short range 50 transceivers, or other detectors, are used in their place to create an ad hoc network. Each medical device 2002, 2004 can serve as a node in the ad hoc network, and each node can share information about, for example, the patients 2010, 2012 and the clinicians 2014, 2016 around it. In some 55 embodiments, the medical devices 2002, 2004 are Bluetooth-enabled, though other short range wireless communications standards can also be used.

If the hospital floor 2000 contains a number of medical devices that are arranged densely enough, then the distributed medical devices 2002, 2004 can serve as a network for tracking the location of, for example, Bluetooth-enabled medical device tracking tags 2006, 2008, patient tokens 2018, 2020, and clinician tokens 2022, 2024. In such an embodiment, the physical location of each tracking tag or 65 token may only be identifiable if it is located within the range of a Bluetooth-enabled medical device. In addition, in

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some embodiments, the physical location of each tracking tag or token may not be able to be precisely identified, as each Bluetooth-enabled medical device may only be able to determine that the tracking tag or token is located somewhere within the medical device's detection area. Nevertheless, this level of tracking resolution may be sufficient in many cases.

In the embodiment illustrated in FIG. 20, a location monitoring server may be communicatively coupled to the WiFi access points 2030, 2034. The location monitoring server may be configured to track the estimated position of each medical device 2002, 2004, each patient 2010, 2012, and each clinician 2014, 2016. The location monitoring server may include a display to show this location information. In addition, the location monitoring server, or some other device, may execute logic that can be useful in enhancing features offered by the patient monitoring systems described herein. The location monitoring server may also be communicatively coupled to the medical devices 2002, 2004.

The system illustrated in FIG. 20 can be used, for example, to enhance the patient monitoring systems described herein. As already discussed, the patient monitoring systems described herein are capable of providing notifications to clinicians when, for example, a monitored patient's physiological parameter (e.g., SpO2, respiratory rate, etc.) triggers an alarm. In some embodiments, the clinician assigned to monitor the patient is notified first by, for example, a page, e-mail, text message, etc. If the first-notifying clinician does not respond within a set period of time, the patient monitoring system may be configured to execute an escalation algorithm whereby one or more additional clinicians are notified of the patient's alarm condition. In some embodiments, the clinician notifications that are sent out when an alarm condition exists can be controlled, at least in part, using location-based rules. For example, location-based rules can be used to determine which clinician is notified of an alarm condition initially, and which clinician, or clinicians, are notified if escalation becomes necessary. The location-based rules can receive as inputs information from the system illustrated in FIG. 20 regarding the physical locations of, for example, patients 2010, 2012 and/or clinicians 2014, 2016.

The location-based rules can be dependent upon, for example, the absolute or relative locations of the patient's 2010, 2012 and/or the clinicians 2014, 2016. For example, if the patient 2010 undergoes an alarm condition, that patient's previously assigned clinician can first be notified so long as he or she is present on the same floor of the hospital (or some other domain). In some embodiments, the clinician located the closest to the patient who is experiencing the alarm condition can be notified regardless of whether the clinician was previously assigned to the patient. In some embodiments, the closest clinician to the patient experiencing the alarm condition can be notified only after the regularly-assigned clinician fails to respond within a certain amount of time. In some embodiments, a nearby clinician is notified of the alarm condition if the alarm condition is particularly urgent and requires immediate attention. Many other location-based rules can also be implemented.

Location-based rules can also be used for controlling whether a clinician is permitted to deactivate an alarm. As disclosed herein, the clinician tokens 2022, 2024 may include an input module (e.g., 1416). One use for this input module is to remotely disable an alarm once the clinician has received notification of the alarm and is en route to the patient. However, in some embodiments, a location-based

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rule can be put into place that may prevent a clinician from remotely disabling an alarm if the clinician is, for example, more than some threshold distance away from the patient.

The location information provided by the system illustrated in FIG. 20 can also be used to provide alerts to 5 clinicians when a patient 2010, 2012 strays more than some threshold distance from the monitoring device assigned to the patient. While some examples of location-based rules have been discussed in the context of patient monitoring systems, the information provided by the system illustrated 10 in FIG. 20 can be used to implement a variety of location-based rules for many different kinds of medical devices. Such location-based rules can include, for example, any rule for determining an action to be performed where the selected action is dependent in whole, or in part, upon the estimated 15 physical location of a device, clinician, and/or patient.

In some embodiments, location-based rules can also be provided for configuring the medical devices 2002, 2004 (e.g., to configure patient monitoring settings). For example, patient monitoring devices of the type described herein are 20 sometimes configured with different physiological parameter alarm limits depending upon the patient ward that they are located in. For example, alarm limits for the pulse rates of neonates should generally be set differently than for the pulse rates of adults. Therefore, it may be desirable to 25 provide a notification to a clinician if an attempt is made to monitor a patient located outside of the nursery using a monitoring device whose alarm limits have been set for neonates. This can be done since the location of the medical device can be detected by the system illustrated in FIG. 20. 30 Other monitoring device configuration settings can also be recommended to clinicians, or automatically set, based upon the physical location of the monitoring device. In some embodiments, the configuration settings and techniques disclosed in US Patent Publication 2009/0275844, the entire 35 contents of which are hereby incorporated by reference herein, can be controlled using the location-based rules described herein.

FIGS. 21A-F, FIGS. 22A-E, and FIGS. 23A-C illustrate proximity displays 2100, 2200, 2300 that feature a multisided animation that appears to rotate from a first screen to a preferred screen in response to user proximity. This feature advantageously provides feedback to the user that the monitor has received an identification signal from the user, as described above, and has recognized the user's presence. As examples, the multi-sided presentation may be any of a triangular-shaped, a cubic-shaped or a planar solid having multiple facets and a different screen preference on two or more of the facets. One of ordinary skill will recognize that many other rotating geometric shapes can provide similar suser feedback, including un-faceted shapes such as a sphere or cylinder. These multi-sided presentations are described in further detail below.

FIGS. 21A-F illustrate a proximity display 2100 embodiment that utilizes a rotating triangular solid 2105 to depict 55 transitions between multiple screens that correspond to different display preferences of monitor users that enter or exit proximity to the monitor. In particular, the triangular solid 2105 has a first side 2101, a second side 2102 and a third side 2103 configured to display different user preferences of patient monitoring information in response to user proximity to the display. Further, the triangular solid 2105 is shown to rotate during a transition between the sides 2101, 2102, 2103 so as to provide feedback to a proximate user.

As shown in FIG. 21A, the first side 2101 relating to a first 65 user is shown in the display 2110. As shown in FIG. 21B, when a second user is proximate the display, the monitor

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identifies the second user, as described with respect to FIG. 7 below, and virtually rotates the triangular solid 2105 from the first side 2101 to the second side 2102. As shown in FIG. 21C, the display 2110 then shows the second side 2102, corresponding to the second user's display preference. As shown in FIG. 21D, when a third user enters proximity to the monitor, the monitor identifies the third user and virtually rotates the triangular solid 2105 from the second side 2102 to a third side 2103. As shown in FIG. 21E, the display 2110 then shows the third side 2103, corresponding to the third user's display preference. As shown in FIG. 21F, when the first user is again identified, the display 2110 virtually rotates the triangular solid back to the first side 2101. In this manner, the sides 2101, 2102, 2102 of the triangular solid 2105 are alternatively shown on the display 2110 according to different user preferences and based upon user proximity to the monitor. As described with respect to FIG. 13 if several users are in proximity to the monitor at once, then priority or acknowledgement schemes are utilized to determine which screen to display.

FIGS. 22A-E illustrate a proximity display 2200 embodiment that utilizes a rotating cube 2205 to depict transitions between multiple screens that correspond to different display preferences of monitor users that enter or exit proximity to the monitor. In particular, the cube 2205 has a first side 2201, a second side 2202 and a third side 2203 configured to display different user preferences of patient monitoring information in response to user proximity to the display. Further, the cube 2205 is shown to rotate during a transition between the sides 2201, 2202, 2203 so as to provide feedback to a proximate user, in a manner similar to that described in detail with respect to FIGS. 21A-F, above.

FIGS. 23A-C illustrate a proximity display 2300 embodiment that utilizes a rotating planar solid 2305 to depict transitions between multiple screens that correspond to different display preferences of monitor users that enter or exit proximity to the monitor. In particular, the planar solid 2305 has a first side 2301 and a second side 2302 configured to display different user preferences of patient monitoring information in response to user proximity to the display. Further, the planar solid 2305 is shown to rotate during a transition between the sides 2301, 2302 so as to provide feedback to a proximate user, in a manner similar to that described in detail with respect to FIGS. 21A-F and FIGS. 22A-E, above.

Although some features are described herein with respect to a bedside monitor, a proximity display is applicable to any monitoring device, medical or non-medical and at any location, such as at bedside or at central monitoring, such as a nurse's station. Further, a proximity display is applicable during physiological data collection or other monitor uses, such as historical data review, setting and verification of alarm limits and installation of software updates by medical personnel or equipment maintenance staff, to name a few. Translation of Medical Communication Protocols to Facilitate Communication Between Devices and Systems

Healthcare costs have been increasing and the demand for reasonably-priced, high-quality patient care is also on the rise. Health care costs can be reduced by increasing the effectiveness of hospital information systems. One factor which may affect the efficacy of a health institution is the extent to which the various clinical computer systems employed at the health institution can interact with one another to exchange information.

Hospitals, patient care facilities, and healthcare provider organizations typically include a wide variety of different clinical computer systems for the management of electronic

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healthcare information. Each of the clinical computer systems of the overall IT or management infrastructure can help fulfill a particular category or aspect of the patient care process. For example, a hospital can include patient monitoring systems, medical documentation and/or imaging systems, patient administration systems, electronic medical record systems, electronic practice management systems, business and financial systems (such as pharmacy and billing), and/or communications systems, etc.

The quality of care in a hospital or other patient care 10 facility could be improved if each of the different clinical computer systems across the IT infrastructure were able to effectively communicate with each other. This could allow for the exchange of patient data that is collected by one clinical computer system with another clinical computer 15 system that could benefit from such patient data. For example, this may allow decisions relating to patient care to be made, and actions to be taken, based on a complete analysis of all the available information.

In current practice, individual clinical computer systems 20 can be, and often are, provided by different vendors. As a result, individual clinical computer systems may be implemented using a proprietary network or communication infrastructure, proprietary communication protocols, etc.; the various clinical computer systems used in the hospital 25 cannot always effectively communicate with each other.

Medical device and medical system vendors sometimes develop proprietary systems that cannot communicate effectively with medical devices and systems of other vendors in order to increase their market share and to upsell additional 30 products, systems, and/or upgrades to the healthcare provider. Thus, healthcare providers are forced to make enterprise or system-wide purchase decisions, rather than selecting the best technology available for each type of individual clinical computer system in use.

One example where this occurs is in the area of life-saving technology available for patient monitoring. For example, many different bedside devices for monitoring various physiological parameters are available from different vendors or providers. One such provider may offer a best-in- 40 class device for monitoring a particular physiological parameter, while another such provider may offer the bestin-class device for another physiological parameter. Accordingly, it may be desirable in some circumstances for a hospital to have the freedom to use monitoring devices from 45 more than one manufacturer, but this may not be possible if devices from different manufacturers are incapable of interfacing and exchanging patient information. Accordingly, the ability to provide reasonably-priced, high-quality patient care can be compromised. In addition, since each hospital or 50 patient care facility may also implement its own proprietary communication protocols for its clinical computer network environment, the exchange of information can be further hindered.

The Health Level Seven ("HL7") protocol has been 55 developed to provide a messaging framework for the communication of clinical messages between medical computer systems and devices. The HL7 communication protocol specifies a number of standards, guidelines, and methodologies which various HL7-compliant clinical computer systems can use to communicate with each other.

The HL7 communication protocol has been adopted by many medical device manufacturers. However, the HL7 standard is quite flexible, and merely provides a framework of guidelines (e.g., the high-level logical structure of the 65 messages); consequently, each medical device or medical system manufacturer or vendor may implement the HL7

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protocol somewhat differently while still remaining HL7-compliant. For example, the format of the HL7 messages can be different from implementation to implementation, as described more fully herein. In some cases, the HL7 messages of one implementation can also include information content that is not included in messages according to another HL7 implementation. Accordingly, medical devices or clinical computer systems that are all HL7-compliant still may be unable to communicate with each other.

Consequently, what is needed is a module that can improve the communication of medical messages between medical devices or systems that use different allowed implementations of an established communication protocol (e.g., HL7), thereby increasing the quality of patient care through the integration of multiple clinical computer systems.

FIG. 24A illustrates a first medical device 2405 and a second medical device 2410 that communicate with one another via a translation module 2415. The first medical device 2405 is configured to transmit and receive messages according to a first allowed format or implementation of an accepted electronic medical communication protocol, while the second medical device 2410 is configured to transmit and receive messages according to a second allowed format or implementation of the electronic medical communication protocol. In some embodiments, the first and second protocol formats are different implementations of the HL7 communication protocol. Other electronic medical communication protocols besides HL7 can also be used.

The translation module 2415 receives input messages having the first protocol format from the first medical device 2405 and generates output messages to the second medical device 2410 having the second protocol format. The translation module 2415 also receives input messages having the second protocol format from the second medical device 2410 and generates output messages to the first medical device 2405 having the first protocol format. Thus, the translation module 2415 enables the first and second medical devices 2405, 2410 to effectively and seamlessly communicate with one another without necessarily requiring modification to the communication equipment or protocol implemented by each device.

In certain embodiments, the translation module 2415 determines the protocol format expected by an intended recipient of the input message based on, for example, the information in the input message or by referencing a database that stores the protocol format used by various devices, and then generates the output message based on the protocol format used by the intended recipient device or system. The output message can be generated based upon a comparison with, and application of, a set of translation rules 2420 that are accessible by the translation module 2415.

The translation rules 2420 can include rules that govern how to handle possible variations between formatting implementations within a common protocol. Examples of variations in formatting implementation of an electronic medical communication protocol include, for example, the delimiter or separator characters that are used to separate data fields, whether a particular field is required or optional, the repeatability of portions of the message (e.g., segments, fields, components, sub-components), the sequence of portions of the message (e.g., the order of fields or components), whether a particular portion of a message is included, the length of the message or portions of the message, and the data type used for the various portions of the message.

In certain embodiments, the translation rules **2420** define additions, deletions, swappings, and/or modifications that should be performed in order to "translate" an input message

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that adheres to a first HL7 implementation into an output message that adheres to a second HL7 implementation. The output message can have, for example, different formatting than the input message, while maintaining all, or a portion of, the substance or content of the input message.

In addition to translating between different implementations of a common electronic medical communication protocol (e.g., different formatting of HL7 messages), the translation module 2415 can also be configured to translate between input and output messages adhering to different 10 communication protocols. In some embodiments, the translation module 2415 is capable of responding to and translating messages from, for example, one medical communication protocol to a separate medical communication protocol. For example, the translation module 2415 can 15 facilitate communication between messages sent according to the HL7 protocol, the ISO 11073 protocol, other open protocols, and/or proprietary protocols. Accordingly, an input message sent according to the HL7 protocol can be translated to an output message according to a different 20 protocol, or vice-versa.

The operation of the translation module **2415** and the translation rules **2420** will be described in more detail below. Various embodiments of system architectures including the translation module **2415** will now be described.

In certain embodiments, the first medical device 2405, the second medical device 2410, and the translation module 2415 are communicatively coupled via connection to a common communications network. In some embodiments, the translation module 2415 can be communicatively 30 coupled between the first medical device 2405 and the second medical device 2410 (with or without a communications network) such that all messages between the first and second medical devices 2405, 2410 are routed through the translation module 2415. Other architectures are also possible.

The first and second medical devices 2405, 2410 and the translation module 2415 can be included in, for example, a portion of the physiological monitoring system 200 of FIG. 2 or the clinical network environment 600 of FIG. 6 40 described above. In certain embodiments, the portion of the physiological monitoring system 200 comprises a portion of a messaging sub-system of the physiological monitoring system 200 for supporting the exchange of data between the various clinical computer systems used in the hospital.

In certain embodiments, the translation module 2415 can facilitate communication across multiple networks within a hospital environment. In other embodiments, the translation module 2415 can facilitate communication of messages across one or more networks extending outside of the 50 hospital or clinical network environment. For example, the translation module 2415 can provide a communications interface with banking institutions, insurance providers, government institutions, outside pharmacies, other hospitals, nursing homes, or patient care facilities, doctors' 55 offices, and the like.

In some embodiments, the translation module **2415** of FIG. **24** can be a component of, for example, the patient monitoring system **200** described herein. For example, the translation module **2415** can be communicatively coupled 60 with the hospital network **220** illustrated in FIG. **2**. In such embodiments, the translation module **2415** can facilitate the exchange of patient monitoring information, including, for example, physiological parameter measurements, physiological parameter trend information, and physiological 65 parameter alarm conditions between bedside medical monitor devices, nurses' monitoring stations, a Hospital or Clini-

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cal Information System (which may store Electronic Medical Records), and/or many other medical devices and systems. The translation module **2415** can enable seamless communication between different medical devices and systems, each of which may use a different implementation of an electronic medical communication protocol such as, for example, the HL7 communication protocol, within a clinical or hospital network environment.

In certain embodiments, the translation module 2415 can also facilitate communication between a first medical device that is part of the patient monitoring sub-system and a second medical device that is not part of, or is external to, the patient monitoring system 200. As such, the translation module 2415 can be capable of responding to externally-generated medical messages (such as patient information update messages, status query messages, and the like from an HIS or CIS) and generating external reporting messages (such as event reporting messages, alarm notification messages, and the like from patient monitors or nurses' monitoring stations).

In another embodiment, first and second medical devices 2405, 2410 communicate with each other over a communication bus 2421. Communication bus 2421 can include any one or more of the communication networks, systems, and methods described above, including the Internet, a hospital WLAN, a LAN, a personal area network, etc. For example, any of the networks describe above with respect to FIGS. 1, 2, 6, 7, 19, etc. can be used to facilitate communication between a plurality of medical devices, including first and second medical devices 2405, 2410, discussed above. One such embodiment is illustrated in FIG. 24B.

In FIG. 24B, first medical device 2405 provides a message to the communication bus 2421. The message is intended for receipt by the second medical device 2410; however, because first and second medical devices 2405, 2410 communicate according to different communication protocol format, second medical device 2410 is unable to process the message.

Translation module 2415 monitors the communication bus 2421 for such messages. Translation module receives the message and determines that first medical device 2405 is attempting to communicate with second medical device 2410. Translation module 2415 determines that message translation would facilitate communication between first and second medical devices 2405, 2410. Translation module 2415 therefore utilizes an appropriate translation rule stored in a translation module 2420. Translation module 2420 can include a memory, EPROM, RAM, ROM, etc.

The translation module 2415 translates the message from the first medical device 2405 according to any of the methods described herein. Once translated, the translation module 2415 delivers the translated message to the communication bus 2421. The second medical device 2410 receives the translated message and responds appropriately. For example, the second medical device may perform a function and/or attempt to communication with the first medical device 2405. The translation module 2415 facilitates communication from the second medical device 2410 to the first medical device 2405 in a similar manner.

The first medical device 2405 and the second medical device 2410 can be, for example, any of the medical devices or systems communicatively coupled to the hospital network 222 illustrated in FIG. 2. These medical devices or systems can include, for example, point-of-care devices (such as bedside patient monitors), data storage units or patient record databases, hospital or clinical information systems, central monitoring stations (such as a nurses' monitoring

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station), and/or clinician devices (such as pagers, cell phones, smart phones, personal digital assistants (PDAs), laptops, tablet PCs, personal computers, pods, and the like).

In some embodiments, the first medical device **2405** is a patient monitor for communicatively coupling to a patient for tracking a physiological parameter (e.g., oxygen saturation, pulse rate, blood pressure, etc.), and the second medical device **2410** is a hospital information system ("HIS") or clinical information system ("CIS"). In some embodiments, the patient monitor can communicate physiological parameter measurements, physiological parameter alarms, or other physiological parameter measurement information generated during the monitoring of a patient to the HIS or CIS for inclusion with the patient's electronic medical records maintained by the HIS or CIS.

In some embodiments, the first medical device **2405** is an HIS or CIS and the second medical device **2410** is a nurses' monitoring station, as described herein. However, the translation module **2415** can facilitate communication between a 20 wide variety of medical devices and systems that are used in hospitals or other patient care facilities. For example, the translation module **2415** can facilitate communication between patient physiological parameter monitoring devices, between a monitoring device and a nurses' moni- 25 toring station, etc.

Using the translation module **2415**, a patient monitoring sub-system, such as those described herein (e.g., physiological monitoring system **200**), can push data to the HIS or pull data from the HIS even if the HIS uses a different implementation of the HL7 protocol, or some other electronic medical communication protocol.

In certain embodiments, the patient monitoring sub-system can be configured to push/pull data at predetermined intervals. For example, a patient monitor or clinician monitoring station can download patient data automatically from the HIS at periodic intervals so that the patient data is already available when a patient is connected to a patient monitor. The patient data sent from the HIS can include admit/discharge/transfer ("ADT") information received upon registration of the patient. ADT messages can be initiated by a hospital information system to inform ancillary systems that, for example, a patient has been admitted, discharged, transferred or registered, that patient information has been updated or merged, or that a transfer or discharge has been canceled.

In other embodiments, the patient monitoring sub-system can be configured to push/pull data to/from the HIS only when the HIS is solicited by a query. For example, a 50 clinician may make a request for information stored in a patient's electronic medical records on the HIS.

In still other embodiments, the patient monitoring subsystem can be configured to push/pull data to/from the HIS in response to an unsolicited event. For example, a physiological parameter of a patient being monitored can enter an alarm condition, which can automatically be transmitted to the HIS for storing in the patient's electronic medical records. In yet other embodiments, any combination of the above methods or alternative methods for determining when to communicate messages to and from the HIS can be employed.

Example system architectures and example triggers for the communication of messages involving the translation module **2415** have been described. Turning now to the 65 operation of the translation module, FIGS. **25A-25**D illustrate an example medical message at different phases or 52

steps of a translation process. The translation process will be described in more detail below in connection with FIGS. 26, 27A and 27B.

FIG. 25A illustrates an example ADT input message 2505 received by the translation module 2415 from an HIS. The ADT input message 2505 is implemented according to the HL7 communication protocol and contains information related to the admission of a patient to a hospital. The ADT message 2505 includes multiple segments, including a message header segment 2506, an event segment, a patient identification segment, a patient visit segment, role segments, a diagnosis segment, and multiple custom segments.

In some embodiments, the message header ("MSH") segment 2506 defines how the message is being sent, the field delimiters and encoding characters, the message type, the sender and receiver, etc. The first symbol or character after the MSH string can define the field delimiter or separator (in this message, a "caret" symbol). The next four symbols or characters can define the encoding characters. The first symbol defines the component delimiter ("~"), the second symbol defines the repeatable delimiter ("\"), and the fourth symbol defines the sub-component delimiter ("&"). All of these delimiters can vary between HL7 implementations.

In some embodiments, the example header segment 2506 further includes the sending application ("VAFC PIMS"), the receiving application ("NPTF-508"), the date/time of the message ("20091120104609-0600"), the message type ("ADT~A01"), the message control ID ("58103"), the processing ID ("P"), and the country code ("USA"). As represented by the consecutive caret symbols, the header segment also contains multiple empty fields.

FIG. 25B illustrates the message header segment 2506 after it has been parsed into fields or elements based on an identified field delimiter (the caret symbol). In certain embodiments, the parsed input message comprises an XML message that is configured to be transformed according to extensible stylesheet language transformation (XSLT) rules.

In certain embodiment, the parsed input message can be encoded. FIG. **25**C illustrates the parsed message header segment of the input message after being encoded (e.g., using a Unicode Transformation Format-8 ("UTF-8") encoding scheme).

The encoded message header segment shows some of the various data types that can be used in the message. For example, the sending application ("VAFC PIMS") of the third parsed field and the receiving application ("NPTF-508") of the fifth parsed field are represented using a hierarchic designator ("HD") name data type. The date/time field (the seventh parsed field) is represented using the time stamp ("TS") data type. The processing ID field (the eleventh parsed field) is represented using the processing type ("PT") data type. The fields that do not include a data type identifier are represented using the string ("ST") data type. Other possible data types include, for example, coded element, structured numeric, timing quantity, text data, date, entry identifier, coded value, numeric, and sequence identification. The data types used for the various fields or attributes of the segments can vary between formatting implementations.

FIG. 25D illustrates an example output message 2510 from the translation module 2415 based on the example input message 2505 of FIG. 25A. The output message 2510 includes a message acknowledgement segment 2512.

Turning to the operation of the translation module, the translation module 2415 can, for example, create, generate,

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or produce an output message that is reflective of the input message based on an application of the set of translation rules **2420**. In some embodiments, the translation module **2415** can, for example, translate, transform, convert, reformat, configure, change, rearrange, modify, adapt, alter, or 5 adjust the input message based on a comparison with, and application of, the set of translation rules **2420** to form the output message. In some embodiments, the translation module **2415** can, for example, replace or substitute the input message with an output message that retains the content of 10 the input message but has a new formatting implementation based upon a comparison with, and application of, the set of translation rules **2420**.

FIG. 26 illustrates a translation process 2600 for generating an output message based on an input message and a 15 comparison with the set of translation rules 2420 associated with the translation module 2415. The translation process 2600 starts at block 2602 where the translation module 2415 receives an input message from a first medical device.

At block 2604, the translation module 2415 determines 20 the formatting implementation of the input message and the formatting implementation to be used for the output message. In certain embodiments, the input message can include one or more identifiers indicative of the formatting implementation. In some embodiments, the determination of the 25 formatting implementation can be made, for example, by analyzing the message itself by identifying the delimiter or encoding characters used, the field order, the repeatability of segments, fields, or components, the data type of the fields, or other implementation variations. In certain embodiments, 30 the translation module 2415 can separate or parse out the formatting from the content of the message (as shown in FIG. 25B) to aid in the determination of the formatting implementation. In some embodiments, the translation module 2415 determines the formatting implementation of the 35 input message by referencing a database that stores the implementation used by each device with which the translation module 2415 has been configured to interface.

In certain embodiments, the determination of the formatting implementation required by the output message can also 40 be determined from the input message. For example, the input message can include a field that identifies the intended recipient application, facility, system, device, and/or destination. The input message can alternatively include a field that identifies the type of message being sent (e.g., ADT 45 message) and the translation module 2415 can determine the appropriate recipient from the type of message being sent and/or the sending application, device, or system. The translation module 2415 can then determine the formatting implementation required by the intended recipient of the 50 input message.

At decision block 2605, the translation module 2415 determines whether a rule set has been configured for the translation from the identified formatting implementation of the input message to the identified formatting implementation to be used for the output message. The rule set may have been manually configured prior to installation of the translation module software or may have been automatically configured prior to receipt of the input message. If a rule set has already been configured, then the translation process 60 2600 continues to block 2606. If a rule set has not been configured, then a rule set is configured at block 2607. The configuration of the rule set can be performed as described below in connection with FIGS. 28 and 29A-29D. The translation process 2600 then continues to block 2608.

At block 2606, the translation module 2415 identifies the pre-configured rules from the set of translation rules 2420

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that govern translation between the determined formatting implementation of the input message and the formatting implementation of the output message. In some embodiments, the identification of the pre-configured rules can be made manually.

At block 2608, the translation module 2415 generates an output message based on the configured rule set(s) of the translation rules 2420. In certain embodiments, the output message retains all, or at least a portion of, the content of the input message but has the format expected and supported by the intended recipient of the input message.

The translation rules 2420 can include, for example, unidirectional rules and/or bidirectional rules. A unidirectional rule is one, for example, that may be applied in the case of a message from a first medical device (e.g., 2405) to a second medical device (e.g., 2410) but is not applied in the case of a message from the second medical device to the first medical device. For example, a unidirectional rule could handle a difference in the delimiters used between fields for two different formatting implementations of, for example, the HL7 communication protocol. The translation module **2415** can apply a field delimiter rule to determine if the field delimiter is supported by the intended recipient of the input message. If the field delimiter of the input message is not supported by the intended recipient, the field delimiter rule can replace the field delimiter of the input message with a field delimiter supported by the intended recipient.

For example, an input message from an input medical device can include a formatting implementation that uses a "caret" symbol ("^") as the field delimiter or separator. However, the formatting implementation recognized by the intended recipient medical device may use a "pipe" symbol ("|") as the field delimiter. The translation module 2415 can identify the field delimiter symbol used in the formatting implementation recognized by the intended recipient medical device from the set of translation rules **2420** and generate an output message based on the input message that uses the pipe field delimiter symbol instead of the caret field delimiter symbol used in the input message. The rule to substitute a pipe symbol for a caret symbol would, in this case, only apply to messages that are sent to a recipient device that recognizes the pipe symbol as a field delimiter. This rule could be accompanied by a complementary rule that indicates that a caret symbol should be substituted for a pipe symbol in the case of a message that is intended for a recipient device that is known to recognize the caret symbol as the field delimiter.

Another unidirectional rule can handle the presence or absence of certain fields between different formatting implementations. For example, an input message from an input medical device can include fields that would not be recognized by the intended recipient medical device. The translation module 2415 can generate an output message that does not include the unrecognized or unsupported fields. In situations where an input message does not include fields expected by the intended recipient medical device, the set of translation rules 2420 can include a rule to insert null entries or empty "" strings in the fields expected by the intended recipient medical device and/or to alert the recipient device of the absence of the expected field. The sender device may also be notified by the translation module 2415 that the recipient device does not support certain portions of the message.

Other unidirectional rules can facilitate, for example, the conversion of one data type to another (for example, string ("ST") to text data ("TX") or structured numeric ("SN") to numeric ("NM")), and the increase or decrease in the length

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of various portions of the message. Unidirectional rules can also be used to handle variations in repeatability of portions of the message. For example, the translation module 2415 can apply a field repeatability rule to repeated instances of a segment, field, component, or sub-component of the message to determine how many such repeated instances are supported by the recipient device, if any, and deleting or adding any repeated instances if necessary. For example, a phone number field of a patient identification segment can be a repeatable field to allow for entry of home, work, and 10 cell phone numbers.

Bidirectional rules can also be used. Such rules may apply equally to messages between first and second medical devices (e.g., 2405, 2410) regardless of which device is the sender and which is the recipient. A bidirectional rule can be 15 used to handle changes in sequence, for example. In certain implementations, an input message from an input medical device can include a patient name field, or fields, in which a first name component appears before a last name component. However, the intended recipient medical device may 20 be expecting an implementation where the last name component appears before the first name component. Accordingly, the set of translation rules 2420 can include a bidirectional rule to swap the order of the first and last name components when communicating between the two medical 25 devices, or between the two formatting implementations. In general, field order rules can be applied to determine whether the fields, components, or sub-components are in the correct order for the intended recipient and rearranging them if necessary. Other bidirectional rules can be included 30 to handle, for example, other sequential variations between formatting implementations or other types of variations.

The translation rules 2420 can also include compound rules. For example, a compound rule can include an if-then sequence of rules, wherein a rule can depend on the outcome 35 of another rule. Some translation rules 2420 may employ computations and logic (e.g., Boolean logic or fuzzy logic),

As discussed above, the messages communicated over the hospital-based communication network can employ the HL7 40 protocol. FIGS. 27A and 27B illustrate translation processes 2700A, 2700B in which HL7 messages are communicated between a HIS and a medical device over a hospital-based communications network or a clinical network. The translation processes 2700A, 2700B will be described with the 45 assumption that the rules governing "translation" between the first and second HL7 formats have already been config-

FIG. 27A illustrates a translation process 2700A in which the translation module 2415 facilitates communication of an 50 HL7 message, such as the ADT message of FIG. 25A, from an HIS having a first HL7 format to an intended recipient medical device, such as a patient monitor or a clinician monitoring station, having a second HL7 format.

The translation process 2700A starts at block 2701, where 55 the translation module 2415 receives an input message having a first HL7 format from the HIS. In certain embodiments, the input message includes information regarding, for example, the admission of a patient and/or patient identification and patient medical history information from an 60 electronic medical records database.

At block 2703, the translation module 2415 determines the formatting implementation of the input message and the formatting implementation to be used for the output message. These determinations can be made in a similar manner 65 or multiple rule sets. For example, the translation module to the determinations discussed above in connection with block 2604 of FIG. 26.

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At block 2705, the translation module 2415 identifies the rules that govern translation between the determined HL7 format of the input message and the HL7 format of the output message and generates an output message having the second HL7 format based on the identified rules. In certain embodiments, the output message retains the content of the input message sent by the HIS but has the format expected and supported by the intended recipient of the input mes-

At block 2707, the translation module 2415 can output the output message to the intended recipient over the hospitalbased communications network. In certain embodiments, the intended recipient can transmit an acknowledgement message back to the hospital information system acknowledging successful receipt or reporting that an error occurred.

FIG. 27B illustrates a translation process 2700B in which the translation module 2415 facilitates communication of an HL7 message from a medical device, such as a patient monitor, having a first HL7 format to an HIS having a second HL7 format. For example, the patient monitor can transmit reporting event data m such as patient alarm data, to the HIS to store in the patient's electronic medical records.

The translation process 2700B starts at block 2702, where the translation module 2415 receives an input message having a first HL7 format from the medical device. In certain embodiments, the input message includes patient monitoring data or alarm data regarding one or more physiological parameters of the patient being monitored for storage in an electronic medical records database associated with the HIS.

At block 2704, the translation module 2415 determines the formatting implementation of the input message and the formatting implementation to be used for the output message. These determinations can be made in a similar manner to the determinations discussed above in connection with block 2604 of FIG. 26.

At block 2706, the translation module 2415 identifies the rules that govern translation between the determined HL7 format of the input message and the HL7 format of the output message and generates an output message having the second HL7 format based on the identified rules. In certain embodiments, the output message retains the content of the input message sent by the medical device but has the format expected and supported by the HIS.

At block 2708, the translation module 2415 can output the output message to the hospital information system over the hospital-based communications network. In certain embodiments, the HIS can transmit an acknowledgement message back to the medical device acknowledging successful receipt or reporting that an error occurred.

FIGS. 26, 27A and 27B described the operation of the translator module 2415. FIGS. 28 and 29A-29D will be used to illustrate the description of the configuration of the translation rules 2420.

The translation rules 2420 can be implemented as one or more stylesheets, hierarchical relationship data structures, tables, lists, other data structures, combinations of the same, and/or the like. In certain embodiments, the translation rules 2420 can be stored in local memory within the translation module 2415. In other embodiments, the translation rules 2420 can be stored in external memory or on a data storage device communicatively coupled to the translation module 2415.

The translation module 2415 can include a single rule set 2415 can include a separate rule set for each medical device/system and/or for each possible communication pair

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of medical devices/systems coupled to the network or capable of being coupled to the network. In some embodiments, the translation module **2415** can include a separate rule set for each possible pair of formatting implementations that are allowed under a medical communication protocol 5 such as, for example, the HL7 protocol.

In certain embodiments, the translation rules 2420 can be manually inputted using, for example, the messaging implementation software tool 2800 illustrated in FIG. 28. For example, the software developer for a particular hospital 10 network can determine the protocol message formats used by the devices and/or systems that are or can be coupled to the hospital network and then manually input rules to facilitate "translation" between the various protocol message formats supported or recognized by the devices and/or 15 systems.

FIG. 28 illustrates an example screenshot from a messaging implementation software tool 2800 for manually configuring translation rules 2420 to be used by the translation module **2415**. The screenshot from the messaging imple- 20 mentation software tool 2800 illustrates various parameters that may differ between formatting implementations of an electronic medical communication protocol, such as HL7. The screenshot also includes areas where a user can input information that defines, or is used to define, translation 25 rules for converting between different HL7 implementations. In some embodiments, the messaging implementation software tool 2800 stores a variety of pre-configured rule sets based, for example, on known communication protocol implementations of various medical devices. In such 30 embodiments, a user may configure one or more translation rules 2420 to be used in communications involving such devices by entering identification information, such as the device manufacturer, model number, etc. Based on this identification information, the messaging implementation 35 tool 2800 can identify a pre-configured set of translation rules for communication with that device.

In other embodiments, the translation rules 2420 can be automatically generated. For example, the automatic generation of a new set, or multiple sets, of rules can be 40 triggered by the detection of a newly recognized "communicating" medical device or system on a network. In certain embodiments, the automatic generation of a new set or multiple sets of rules can occur at the time a first message is received from or sent to a new "communicating" medical 45 device or system coupled to the network. In still other embodiments, the automatic generation of rule sets includes updating or dynamically modifying a pre-existing set of rules.

The automatic generation of translation rule sets can be 50 carried out in a variety of ways. For example, in some embodiments, the translation module 2415 can automatically initiate usage of a pre-configured set of translation rules 2420 based upon, for example, the make and model of a new device that is recognized on the network. In certain 55 embodiments, the translation module 2415 can request one or more messages from the new device or system and then analyze the messages to determine the type of formatting being implemented, as illustrated by the automatic rule configuration process 2900A of FIG. 29A. The automatic 60 rule configuration process 2900A starts at block 2901, where the translation module 2415 receives one or more messages from a detected medical device or system on the network. The messages can be received upon transmission to an intended recipient medical device or system or in response 65 to a query sent by the translation module 2415 or another medical device or system coupled to the network.

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At block 2903, the translation module 2415 determines the protocol of the one or more received messages by, for example, analyzing the message or by consulting a database that indicates what communication protocol/format is implemented by each medical device or system on the network. In certain embodiments, the translation module 2415 is configured to handle medical messages implemented using a single common protocol, such as HL7. Accordingly, if a determination is made that the received messages are implemented using a non-supported or non-recognized protocol, the translation module can ignore the messages received from the detected medical device or system, output an alert or warning, or allow the messages to be sent without being translated

At block 2905, the translation module 2415 determines the formatting implementation of the received message(s). In certain embodiments, the received messages can include one or more identifiers indicative of the formatting implementation. In other embodiments, the determination of the formatting implementation can be made, for example, by analyzing the message itself by checking field order, the delimiter or encoding characters used, or other implementation variations. In certain embodiments, the translation module 2415 can separate or parse out the formatting from the content of the message to aid in the determination of the formatting implementation.

At block 2907, the translation module 2415 configures one or more rules or rule sets to handle messages received from and/or sent to the detected medical device or system. In certain embodiments, the configuration of the rules involves the creation or generation of new rules. In other embodiments, the configuration of the rules involves the alteration or updating of existing rules. The configured rules or rule sets can be included with the translation rules 2420. If a set of rules already exists for the formatting implementation used by the new device or system, then the configuration of new translation rules may not be required. Instead, existing translation rules can be associated with the new device or system for use in communication involving that device or system. In other embodiments, the translation module 2415 can create a new set of rules geared specifically for the new device or system or can modify an existing set of rules based on subtle formatting variations identified.

In other embodiments, the translation module 2415 can generate test message(s) that may be useful in identifying the communication protocol and implementation used by a device or system. For example, the translation module can generate test messages to cause the newly detected device or system to take a particular action (e.g., store information) and then query information regarding the action taken by the newly detected device to determine whether or how the test message was understood. This is illustrated by the automatic rule configuration process 2900B of FIG. 29B.

The automatic rule configuration process 2900B starts at block 2902, where the translation module 2415 transmits one or more test, or initialization, messages to a remote device or system detected on a network. The test messages can be configured, for example, to instruct the remote device or system to take a particular action (e.g., store patient information). In certain embodiments, the test messages can be configured to generate a response indicative of the type of formatting recognized or supported by the remote device or system. In other embodiments, the test messages can be configured such that only devices or systems supporting a particular formatting implementation will understand and properly act on the test messages.

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At block 2904, the translation module 2415 queries the remote device or system to receive information regarding the action taken based on the test message sent to the remote device or system to determine whether the test message was understood. For example, if the test message instructed the 5 remote device or system to store patient information in a particular location, the translation module 2415 can query the information from the location to determine whether the test message was understood. If the test message was not understood, the translation module 2415 can, for example, 10 continue sending test messages of known formatting implementations until a determination is made that the test message has been understood.

At block 2906, the translation module 2415 determines the protocol and formatting implementation based on the 15 information received. As an example, in certain embodiments, the test message can include an instruction to store patient name information. The test message can include a patient name field having a first name component followed by a surname component. The translation module **2415** can 20 then query the remote device or system to return the patient surname. Depending on whether the patient surname or the first name is returned, this query can be useful in determining information about the order of fields in the formatting implementation being used by the remote device or system. 25 As another example, the test messages can instruct the detected device or system to store repeated instances of a component. The translation module 2415 can then query the device or system to return the repeated instances to see which, if any, were stored. This repeatability information 30 can also be useful in determining whether certain fields are allowed to be repeated in the formatting implementation being used by the remote device for system, and, if so, how many repeated instances are permitted.

At block **2908**, the translation module **2415** configures 35 one or more rules to handle messages received from and/or sent to the detected medical device or system. For example, the rules can convert messages from the message format used by a first medical device to that used by a second medical device, as described herein. In certain embodiments, the configuration of the rules involves the creation or generation of new rules. In other embodiments, the configuration of the rules involves the alteration or updating of existing rules. If a set of rules already exists for the formatting implementation used by the new device or system, then 45 the configuration of new translation rules may not be required. Instead, existing translation rules can be associated with the new device or system for use in communication involving that device or system.

FIGS. 29C and 29D illustrate automatic rule configuration 50 processes performed by the translation module 2415 for messages utilizing the HL7 protocol. The HL7 protocol can be used, for example, to communicate electronic messages to support administrative, logistical, financial, and clinical processes. For example, HL7 messages can include patient 55 administration messages, such as ADT messages, used to exchange patient demographic and visit information across various healthcare systems.

The automatic rule configuration process 2900C illustrated in FIG. 29C is similar to the process 2900A illustrated on FIG. 29A. At block 2911, the translation module 2415 receives one or more messages from an HL7 medical device. At block 2915, the translation module 2415 determines the formatting implementation of the HL7 medical device from the one or more messages received. As discussed above, the 65 determination of the formatting implementation can be made, for example, by checking field order or sequence,

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field delimiter characters, repeatability, cardinality, and other HL7 implementation variations.

At block 2917, the translation module 2415 configures one or more rules to handle messages received from and/or sent to the HL7 medical device. In certain embodiments, the configuration of the rules involves the creation or generation of new rules for the detected formatting implementation. In other embodiments, the configuration of the rules involves the dynamic alteration or updating of existing rules. If a set of rules already exists for the formatting implementation used by the new HL7 medical device, then the configuration of new translation rules may not be required. Instead, existing translation rules can be associated with the new HL7 medical device for use in communication involving that device.

The automatic rule configuration process 2900D illustrated in FIG. 29D is similar to the process 2900B illustrated in FIG. 29B. At block 2912, the translation module 2415 transmits one or more test, dummy, or initialization messages to an HL7 medical device. In other embodiments, the translation module 2415 can cause one or more test messages to be transmitted to the new HL7 medical device from another HL7 medical device. As described above, the test messages can include messages having known HL7 formats configured to determine whether the HL7 device understands the test messages. The test messages can include test ADT messages, for example.

At block 2914, the translation module 2415 queries the HL7 medical device to receive information regarding an action taken or information stored in response to the test message. At block 2916, the translation module 2415 determines the formatting implementation of the HL7 device based on the information received. In certain embodiments, the translation module 2415 can analyze the information received to determine whether the test message or messages were properly understood. If none of the test messages were properly understood, the translation module 2415 can send additional test messages having other known HL7 formats and repeat blocks 2914 and 2916.

At block 2918, the translation module 2415 configures one or more translation rules to handle messages received from and/or sent to the detected HL7 medical device. In certain embodiments, the configuration of the translation rules involves the creation or generation of new translation rules. In other embodiments, the configuration of the rules involves the alteration or updating of existing rules. If a set of translation rules already exists for the formatting implementation used by the new HL7 medical device, then the configuration of new translation rules may not be required. Instead, existing translation rules can be associated with the new HL7 medical device for use in communication involving that HL7 medical device.

The automatic rule configuration processes described above can be triggered by the detection of a network device or system by the translation module **2415**. The medical devices referred to in FIGS. **29**A-**29**D can include any of the devices or systems illustrated in FIG. **2** and discussed above.

In some embodiments, the automatic generation of translation rules can advantageously occur post-installation and post-compilation of the messaging sub-system software, which includes the translation module 2415. In certain embodiments, the automatic generation or dynamic modification of the translation rules 2420 can occur without having to recompile or rebuild the translation module software. This feature can be advantageous in terms of effi-

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ciently complying with U.S. Food and Drug Administration ("FDA") requirements regarding validation of software used in healthcare environments.

Take, for example, a situation where a medical device manufacturer plans to use the translation module 2415 to facilitate communication between a particular medical device or system that is to be installed in a hospital (e.g., a patient monitoring system, as described herein), or other patient care facility, and other devices or systems that are already installed at the hospital (e.g., the HIS or CIS). Any software required for the operation of the new medical device to be installed may be at least partially validated for FDA compliance prior to installation at the hospital despite the fact that, for example, the HL7 implementations of other 15 existing devices or systems at the hospital may still be unknown. For example, any aspects of the software for the new medical device that are dependent upon receiving messages from other hospital devices can be validated pre-installation as being capable of fully and correctly 20 operating when the expected message format is received. Then, once the medical device is installed at the hospital, the validation of the software can be completed by showing that the translation module 2415 is able to provide messages of the expected format to the newly installed device. In this 25 way, FDA validation tasks can be apportioned to a greater extent to the pre-installation timeframe where they can be more easily carried out in a controlled manner rather than in the field.

In addition, the translation module 2415 can further help 30 streamline FDA validation, for example, when a medical device or system is expected to be installed at different hospitals whose existing devices use, for example, different implementations of the HL7 protocol. Normally, this type of situation could impose the requirement that the entire func- 35 tionality of the software for the new medical device be completely validated at each hospital. However, if the translation module 2415 is used to interface between the new medical device and the hospital's existing devices, then much of the software functionality could possibly be vali- 40 dated a single time prior to installation, as just described. Then, once installed at each hospital, the software validation for the medical device can be completed by validating that correct message formats are received from the translation module (the translation rules for which are field-customiz- 45 able). This may result in making on-site validation procedures significantly more efficient, which will advantageously enable more efficient FDA compliance in order to bring life-saving medical technology to patients more quickly by the use of field-customizable translation rules. 50 Patient Monitoring Reports

Devices and methods for monitoring physiological parameters such as blood oxygen saturation, pulse rate, blood pressure, and many others, are described herein. Such medical monitoring devices are often programmed with 55 alarm limits to automatically detect when a physiological parameter has a value that is, for example, outside the range of values considered safe or healthy for that particular physiological parameter. In some embodiments, when such an alarm condition is detected, various actions can be taken. 60 For example, the bedside medical monitor can emit an audible or visual alarm. In addition, in some cases, after the alarm condition has persisted for some set amount of time (e.g., 5 sec.), the alarm condition can be displayed at, for example, a central patient monitoring station, as described 65 herein. Moreover, if the alarm condition continues to persist for some set amount of time (e.g., 10 sec.), the clinician

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assigned to care for the patient who is experiencing the alarm condition can be notified by, for example, a pager or other notification device.

The number of detected alarm conditions is, of course, dependent upon the settings for the alarm criteria that indicate an alarm condition. In some embodiments, such alarm criteria can include a threshold value, which may indicate the boundary between values for a physiological parameter that are considered safe or normal, and those that are considered to indicate a medical condition which may require attention from a clinician. The nearer such an alarm threshold is set to values that are common for that particular physiological parameter in healthy individuals under normal circumstances, the larger the number of alarm events that will be expected to be detected. Generally speaking, the closer the alarm criteria come to being satisfied by the normal expected range of values for a given physiological parameter, then the greater the odds of detecting any deviation from the normal range of values that may indicate that the patient is in need of some type of medical intervention (e.g., administration of drugs, CPR, ventilator, etc.). This can be desirable in the sense that it becomes less likely that a patient will experience medical duress without triggering an alarm, which can be referred to as a false negative.

Reduction of false negatives does not come without a cost, however. Namely, alarm criteria for physiological parameters that are successful in reducing false negatives may also increase the rate of false positives, where alarm conditions are detected even though the patient may not be experiencing any clinically significant medical duress. If false positives become too frequent, they can become burdensome to clinicians, who are responsible for investigating alarm conditions, resetting the monitoring devices from the alarm state, etc. In addition, frequent false positives can even put patients at risk by reducing the importance assigned to alarm events by clinicians, whether consciously or subconsciously. Thus, it is desirable to determine alarm criteria for medical monitoring applications that strike a satisfactory balance that limits false negatives to an acceptable rate without unduly increasing false positive alarm events. In some cases, false positives may be preferred to false negatives, especially in circumstances where the consequences of a false negative would be severe to the patient. Such a preference for maintaining the occurrence of false negatives at a relatively low rate can be reflected in the choice of alarm limit criteria. It is not necessarily the case, however, that false positives are always preferred to false negatives. Moreover, alarm criteria that may be satisfactory for one type of patient may be unsatisfactory for other types of patients. The appropriate balance between false positives and false negatives may vary for different medical monitoring applications.

For example, in the case of blood oxygen saturation monitoring, typical SpO2 values of healthy individuals may fall in the range of 95-100%. Therefore, if a patient monitoring device were configured with an SpO2 alarm threshold of 94%, the number of false positive alarm events may be relatively high. In contrast, if the SpO2 alarm threshold were set at 92%, then the number of false positives would likely be reduced, but the number of false negatives may increase beyond a satisfactory level in some medical monitoring applications. Therefore, devices and methods for providing data that would aid in the selection of an alarm threshold that would reduce false positives while still maintaining false negatives at or below a satisfactory level would be very

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useful. Such devices and methods could be used for establishing alarm criteria for a wide variety of physiological parameters.

FIG. 30 is an example graph 3000 of the distribution of alarm events for a given physiological parameter as a 5 function of alarm limit values. The graph 3000 plots the number of detected alarm conditions versus a range of alarm limit values. The graph 3000 reflects, for example, a hypothetical situation where physiological parameter alarm data is collected from a statistically-significant number of 10 patients of a particular type (e.g., cardiac patients) over the course of a statistically-significant period of time using a range of different alarm limit values. Of course, the distribution of alarm events as a function of alarm limit values will generally vary for different physiological parameters.

The graph 3000 shows a set of linearly increasing alarm limit values on the x-axis. The corresponding number of detected alarm conditions for each alarm limit value is plotted on the y-axis. As illustrated, for this particular physiological parameter, the number of detected alarm conditions generally decreases as the alarm limit value is increased. Each bar in the graph 3000 may be representative of, for example, a combination of false positive alarm events and correctly detected alarm events (e.g., detection of an alarm event when the patient was actually in need of medical 25 assistance).

The dashed vertical line 3002 represents one possible alarm limit threshold value. When the physiological parameter value is above the threshold indicated by the dashed vertical line 3002, for example, an alarm condition is 30 detected, whereas when the physiological parameter value is below the threshold, no alarm condition is detected. The dashed vertical line 3004 represents another possible alarm limit value

As shown on the graph 3000, the illustrated alarm limit 35 values 3002, 3004 are only separated by two values on the x-axis. However, the number of alarms detected using each of the two illustrated alarm thresholds 3002, 3004 is approximately halved in going from the first alarm threshold 3002 to the second alarm threshold 3004. Thus, in this case, 40 the number of alarm thresholds is non-linearly related to variation in the alarm limit values. This is illustrative of the realization that, in some cases, a hospital or other patient care facility could make relatively small changes to the alarm criteria used in monitoring a physiological parameter 45 while disparately impacting the number of detected alarms and false positives. In some cases, the number of detected alarms could be significantly reduced, for example, by reducing the number of false positives without necessarily increasing the risk of false negatives in a clinically-signifi- 50 cant way. Even if, however, no disproportionate change in the number of false positives can be achieved with a relatively small adjustment to alarm criteria (e.g., an alarm threshold value), the techniques described herein may still be useful in some circumstances for incrementally reducing 55 the number of false positives in a safe manner. Of course, changes to the alarm criteria used for monitoring patients are not to be taken lightly; generally speaking, hospital administrators or other responsible personnel should authorize any changes to alarm criteria.

In some embodiments, a device and/or system is provided for collecting medical monitoring information from patients in a patient care domain. For example, the medical monitoring information can be collected from a clinically-significant number of patients over a clinically-significant of period of time. In some embodiments, the patient care domain is a group of patients of a similar type, or a group

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of patients who exhibit similar medical characteristics, conditions, defects, etc., and, as such, can also be expected to undergo monitoring alarm conditions for similar reasons. For example, the patient care domain could consist of a group of cardiac patients on a hospital floor, etc.

In some embodiments, a number of bedside patient monitors are used to collect physiological signals from the patients. The raw physiological signals can be processed by the bedside patient monitors. For example, the bedside patient monitors may perform averaging of the raw signals, filtering, etc. The bedside patient monitors may also perform computations to calculate the value of a physiological parameter. The bedside patient monitors may then output an indication of a physiological parameter value (e.g., SpO2, pulse rate, blood pressure, etc.) and its trending over time. Physiological information such as the raw physiological signals, processed physiological signals, and/or calculated physiological parameter values, for example, for each of the patients can then be transmitted to, and stored by, for example, a central repository. In some embodiments, this information is stored by a networked database such as, for example, the round-robin database 722 described herein. In some embodiments, the central repository can store medical monitoring information for the patients in a particular domain (e.g., a hospital ward) over a period of time such as a week, or a month, for example.

At the initial time of monitoring, an algorithm, or algorithms, may be applied to the raw physiological signals, processed physiological signals, and/or computed physiological parameter values for detecting whether a first set of alarm criteria are satisfied. This can be done by, for example, each bedside patient monitor for each patient in the patient care domain. The first set of alarm criteria are, for example, those criteria implemented in the patient monitoring devices that perform real-time monitoring functions to detect alarm conditions. If the alarm criteria are satisfied, then an alarm can be generated, as described herein. The central repository can also be used to store the occurrences of alarm conditions for each patient.

In some embodiments, once a statistically-significant amount of patient monitoring data has been collected at the central repository, a reporting module can access the central repository and use these data to simulate the alarm events that would have been detected had the patient monitoring devices in the patient care domain used a different set of alarm criteria than those that were actually used at the time of monitoring.

In some embodiments, the reporting module is used in conjunction with the patient monitoring systems described herein (e.g., those shown in FIGS. 1, 2, 6, 7, 19, and others). In some embodiments, the reporting module is a server or other computing device communicatively coupled to a network of bedside patient monitoring devices, a central monitoring station, a database, and other devices that can form a patient monitoring system. The reporting module can include a processor for analyzing patient monitoring data. The reporting module can also include, for example, electronic memory for storing patient monitoring data.

In some embodiments, if the central repository includes, for example, physiological parameter trend data for each of the patients, then the reporting module can access the trend data and can re-analyze it using, for example, the same algorithm, or algorithms, previously used by the bedside patient monitoring devices for detecting whether alarm criteria are satisfied. However, in this case a second alarm criteria can be used that is different from the first alarm criteria that was used to detect alarm conditions, for

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example, in real time when the patient monitoring data was actually collected. In some embodiments, the reporting module re-analyzes the stored patient monitoring data using multiple different new alarm criteria. Thus, the reporting module can generate information showing how the number of alarms detected changes as a function of changing alarm criteria.

FIG. 31 is a flow chart that illustrates a method 3100 for determining the variation in identified alarm conditions resulting from varying alarm criteria. The method 3100 10 begins at block 3102 where physiological parameter data is collected from a group of patients in a patient care domain. For example, the physiological parameter data can be collected by a number of different bedside patient monitoring devices distributed throughout a patient care facility. The 15 collected physiological parameter data can include, for example, any type of information relevant to the physiological parameter being monitored and the patient from whom the physiological parameter data is being collected. Again, some examples of physiological parameter data that can be 20 collected are raw physiological signals, processed physiological signals, calculated values of a physiological parameter, etc.

At block 3104, the physiological parameter data is analyzed to identify alarm conditions based upon a first set of 25 alarm criteria. The alarm criteria can be configurable so as to modify the physiological conditions that will trigger an alarm. In some embodiments, the analysis of the physiological parameter data is performed in substantially real-time by, for example, the bedside patient monitoring devices in order 30 to detect alarm conditions as they occur. The alarm criteria will generally depend upon the particular physiological parameter being monitored. In some embodiments, the alarm criteria is a single threshold value. In some embodiments, the alarm criteria includes multiple threshold values 35 that define, for example, an enclosed range of safe or normal values for the physiological parameter. Other types of alarm criteria can also be used.

At block 3106, the physiological parameter data is stored at, for example, a central repository (e.g., the round-robin 40 database 722). In some embodiments, the central repository stores all, or substantially all, of the physiological parameter data that was collected at block 3102. For example, the central repository can store a physiological information such as the raw physiological signals from each patient, or 45 physiological signals that have already been processed or altered to some extent by, for example, the bedside patient monitoring devices. In addition, the central repository can store information about any alarm conditions that were detected for each patient at block 3104. For example, the 50 central repository can store the timing and type of each alarm condition for each patient.

At block 3108, the physiological parameter data that was previously stored can be analyzed to identify alarm conditions based on a second alarm criteria that is different from 55 the first criteria used at block 3104. This analysis can be performed by, for example, the reporting module described herein. If, for example, in the case of blood oxygen saturation monitoring, detected pulse oximetry signals were analyzed at the actual time of monitoring using an alarm 60 threshold of 94% oxygen saturation, then later at block 3108, the pulse oximetry signals can be re-analyzed using an alarm threshold of 93% oxygen saturation, or 92% oxygen saturation, etc. This analysis of the previously-collected physiological parameter data can be used to simulate the 65 effect of a new alarm threshold in a riskless manner, since patients can still be monitored at, for example, blocks 3102,

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3104 using alarm criteria that are already accepted and validated. This ability to simulate the effect of changing alarm criteria on the alarm conditions that are identified from physiological data is advantageous to hospitals and other patient care facilities as a means of adjusting alarm criteria to be specifically adapted for that particular hospital or patient care facility. Specially adapted alarm criteria are advantageous because alarm criteria that work well at one hospital, or for one type of patient, are not necessarily guaranteed to work well at another hospital, or for another type of patient. This can be due to differences in the type of monitoring equipment that is used, differences in patient population, differences in the type of medical care offered, differences in medical procedures implemented by clinicians, etc.

In some embodiments, the algorithm, or algorithms, that are applied by the reporting module to the collected physiological parameter data at block 3108 are the same as, or substantially similar to, those which were applied at the time of monitoring in order to detect real-time alarm conditions, though this may not be required in all embodiments. In addition, in some embodiments, the physiological parameter data stored at the central repository is the same as, or substantially similar to, the physiological parameter data to which alarm detection algorithms were applied by, for example, bedside patient monitors at the time of collection of the data. In this way, different alarm criteria can be simulated as if they had actually been used at the time of collection of the physiological parameter data to detect real-time alarm conditions.

At block 3110, the reporting module can analyze the effect of the simulated alarm criteria on alarm conditions that are detected. For example, the reporting module can analyze the change, if any, in the number of detected alarm conditions using the new simulated alarm criteria. This information can be provided for each patient and/or for the combined group of patients, for example. In addition, the reporting module can analyze differences in the timing at which alarm conditions were detected. Generally speaking, thereporting module can analyze any change in the number, type, timing, duration, etc. of alarm conditions that are detected when using the second alarm criteria as compared to the alarm conditions detected using the first alarm criteria that were applied at the time of monitoring.

At block 3112, the reporting module can output a report that identifies, explains, summarizes, or otherwise bears upon the effect of the simulated alarm criteria. This report can be beneficial to, for example, hospital administrators in determining whether any changes to the alarm criteria used by, for example, the bedside patient monitors are warranted. For example, as described herein, in some circumstances the alarm criteria could be changed so as to reduce the number of false positives that are detected. The reporting module enhances the ability of hospital administrators to make such decisions because it can provide information about the effect that such changes would have had if they had been previously implemented. Generally speaking, hospital administrators will have the final responsibility for determining whether changes to the alarm criteria can be safely made in order to, for example, reduce false positives without unacceptably increasing false negatives.

FIG. 32 illustrates an example report with a table 3200 showing how simulated alarm criteria affect alarm detection events. The table 3200 includes row entries for five different simulated alarm criteria, though any number of new alarm criteria could be simulated. The table 3200 includes column entries for the number of alarms detected using each simu-

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lated alarm criteria. The number of alarms could be broken down, for example, according to patient, or listed as a total sum of alarms detected for all of the patients for whom physiological parameter data was collected.

The table 3200 also includes column entries for the 5 change in the number of alarms that were detected using each of the simulated alarm criteria as compared to the number of alarms that were detected using the actual alarm criteria applied at the time of collection of the physiological parameter data. This change could be indicated as the 10 difference in the number of alarms, the percent difference, etc.

Many other types of information and information formats exist for reporting the effect of the simulated alarm criteria. FIG. 32 illustrates only an example report that could be 15 generated by the reporting module based upon the simulated alarm criteria. It should be understood that such reports could include a wide variety of information relating to the impact of the simulated alarm criteria to help hospital administrators make a decision as to whether changes to 20 alarm criteria should be made. In addition, such reports can be presented in a wide variety of formats, including tables, charts, graphs, lists, spreadsheets, etc.

FIG. 33 is a flow chart that illustrates another method 3300 for determining the variation in identified alarm conditions that occur as a result of varying alarm criteria. The method 3300 is similar to the method 3100 illustrated in FIG. 31, however, the method 3300 additionally involves determinations of, for example, the expected effect of simulated alarm limits on false positive alarms and false negative 30 alarms.

The method 3300 can proceed through blocks 3302 and 3304 as described above with respect to the method 3100 and blocks 3102, 3104 illustrated in FIG. 31. At block 3306, however, the method 3300 further includes collection of 35 medical intervention data. The medical intervention data can include, for example, records of whether a patient required some type of medical intervention at any point in time while the physiological parameter was being monitored. Such medical interventions could include, for example, the 40 administration of a drug, attention from a physician or nurse (e.g., non-routine attention), attention from a rapid response team, administration of a treatment or procedure, etc. The medical intervention data can also include any pertinent information about the medical intervention such as, for 45 example, the type, the time, and the duration of the medical intervention, the medical cause that necessitated the intervention, relationship to detect alarm events, etc.

In some embodiments, the medical intervention data that is collected at block 3306 is used to determine which, if any, 50 of the alarm conditions detected at block 3304 were false positive alarms and/or which were alarms that represented true indications of medical duress. Later, this information can be used, for example, to determine whether various simulated alarm criteria would have eliminated any identi- 55 fied false positive alarms or whether the simulated alarm criteria would have resulted in non-detection of any alarms that actually did indicate a need for medical intervention (e.g., resulting in a false negative). In addition, the medical intervention data can be used to identify false negatives and 60 to determine whether simulated alarm criteria would have resulted in detection of such false negatives. This information can be analyzed and presented in a report to further aid hospital administrators in making a determination of whether to change alarm criteria used by patient monitoring 65 devices based upon simulated alarm criteria, as described herein.

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The medical intervention data can be obtained in a variety of ways. For example, medical intervention data can be recorded by clinicians as medical interventions become necessary. These records can then be manually imported into the central repository that also stores the collected physiological parameter data. Medical intervention data can be automatically imported into the central repository from the patient's electronic medical record stored in, for example, a Hospital Information System. In some embodiments, the bedside patient monitoring devices can be configured so as to prompt clinicians to enter medical intervention data, for example, after an alarm is disabled. Other techniques for obtaining records of medical interventions can also be used.

If a record of a medical intervention that has been performed on behalf of the patient is, for example, temporally associated with the timing of a detected alarm condition (e.g., they are separated by some length of time less than a pre-determined threshold), this can be taken as a sign of an accurately detected alarm condition. For example, if a detected alarm condition is followed by a medical intervention relatively shortly thereafter, then it can be presumed that the alarm condition required medical attention. If, however, a record of a medical intervention that has been performed is not temporally associated with the timing of any detected alarm condition for that patient, then this can be an indication of a false negative since the medical condition that necessitated the intervention did not trigger an alarm. Later in the method 3300, after various new alarm criteria have been simulated, it can be determined whether such simulated criteria would have detected the false negative, or whether the new simulated criteria would have still detected the alarm condition that was accurately detected by the alarm criteria in place at the time of monitoring.

In some embodiments, medical intervention data can include an automated estimation of whether or not a medical intervention for a given patient has taken place. An estimation of whether or not a medical intervention was required after an alarm detection event can be automatically made based upon, for example, the length of time that a clinician spent with the patient after responding to an alarm event, or whether a physician came to check on the patient within some time limit of a detected alarm event. This information can be collected using the clinician proximity detection devices and systems described herein. For example, in some embodiments, a patient monitoring device can start a timer after an alarm detection event has occurred. If the presence of a physician (e.g., as identified by a clinician token, as described herein) is detected within some predetermined amount of time, then an estimation can be made that the physician visit was in response to the alarm event. As such, the physician visit can be identified as a medical intervention. Similarly, a patient monitoring device can track the amount of time that a clinician (e.g., a nurse) spends in proximity to the patient after silencing an alarm. If the amount of time with the patient exceeds a certain threshold, then it can be inferred that some type of medical intervention was necessary in response to the alarm event.

In addition, an estimate of whether or not medical intervention was required, for example, after an alarm event can be determined by analyzing the physiological parameter data collected for that patient. For example, the reporting module can analyze the trend values for the physiological parameter and determine whether the physiological parameter continued to worsen after the alarm event was detected. In some embodiments, the reporting module can analyze the trend data to determine whether the patient's condition, as indi-

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cated by the trend values of the physiological parameter, was worse 1 min. after the alarm detection event, whether it was worse 5 min. later, and/or whether it was worse 10 min. later. Different time limits can of course also be used. If such an analysis indicates that the patient's condition deteriorated 5 after the alarm event was detected, then this can be taken as an indication that the alarm did in fact indicate that the patient was experiencing medical duress and that the alarm was not a false positive.

As just described, the medical intervention data used in 10 the method 3300 can come from actual records of medical interventions that occurred. Alternatively, or additionally, the medical intervention data used in the method 3300 can be estimated based upon factors such as, for example, the amount of time clinicians spent with the patient in the wake 13 of a detected alarm event or the behavior of the physiological parameter within some relevant time after a detected alarm event. Other factors and methods for estimating the occurrence of a medical intervention can also be used. While medical intervention data that results from actual clinician 20 records may be more accurate and reliable, some such occurrences of medical interventions may go unreported. Estimated medical intervention data can be useful since the reliance upon clinicians to maintain accurate records is reduced, though the estimates may be somewhat less reliable 25 than actual clinician records.

At block 3308, the collected physiological parameter data and the medical intervention data can be stored in, for example, the central repository (e.g., the round-robin database 722) for later analysis by the reporting module. The 30 reporting module can include logic used for correlating the collected medical intervention data with the detected alarm events. For example, the logic can include rules or criteria for determining whether or not a given medical intervention for a patient was related to an alarm condition experienced 35 by that patient. For example, in the case of medical intervention data obtained from actual clinician records, a particular medical intervention for a patient can be correlated with a detected alarm event for that patient if the medical intervention and the alarm event occurred within a certain 40 amount of time of one another. Other methods are also possible for matching medical intervention data with corresponding detected alarm events that were possibly related to the medical intervention. For example, such a correlation can be based upon the type of medical intervention that was 45 performed and the type of physiological parameter for which monitoring data has been obtained. Some medical interventions may be viewed as being particularly likely to be related to a specific physiological parameter. In such cases, the reporting module logic may be configured to make it more 50 likely that such a medical intervention will be marked as being correlated with alarm events triggered by that physi-

At block **3310**, the reporting module analyzes the physiological parameter data using second alarm criteria, for 55 example, as described with respect to FIG. **31** (e.g., block **3108**). At block **3312**, the reporting module can analyze any differences between those alarm conditions identified using the first alarm criteria versus those alarm conditions identified using simulated second alarm criteria. For example, 60 after determining the alarm conditions that would have been detected by the second alarm criteria, the reporting module can determine how many of the true alarm conditions that were correctly identified at the actual time of monitoring using the first alarm criteria would have still been detected 65 if the simulated alarm criteria had instead been implemented. It is desirable that such true alarm conditions still be

detected so as to avoid increasing the number of false negatives. Accordingly, information regarding the number of true alarm conditions that would go undetected using a given simulated alarm criteria can be provided to hospital administrators to aid in determining whether a proposed change to the alarm criteria should be adopted.

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In addition, the reporting module can analyze the effect of the simulated alarm criteria on any false negatives that were identified based on medical intervention data. In some embodiments, the reporting module determines whether the simulated alarm criteria would have detected any false negatives that were not identified by the first alarm criteria actually used by the patient monitoring devices. This can be done, for example, by executing logic designed to determine whether any alarm conditions detected using the simulated alarm criteria are temporally correlated with a previouslyidentified false negative event. If, for example, an alarm condition identified by the simulated alarm criteria precedes the timing of the identified false negative by some period of time less than a given threshold, then this can be taken as an indication that the alarm condition would have been an indicator of the false negative. Other logical tests can also be applied to correlate alarm conditions detected using the simulated alarm criteria with false negatives that have been identified based on medical intervention data.

At block 3314, the reporting module outputs a report that identifies, explains, summarizes, or otherwise bears upon the effect of the simulated alarm criteria. In some embodiments, the report can provide an indication of the effect that the simulated alarm criteria would be expected to have on not only the number of detected alarm events but also the number, percentage, proportion, etc. of, for example, previously undetected false negatives that may have been detected using the simulated alarm criteria. The report can also include an indication of, for example, the number, percentage, proportion, etc. of actual alarm conditions that were correctly identified using the first alarm criteria but may not have been identified using the second alarm criteria. The report can also include other information as well.

FIG. 34 illustrates an example report with a table 3400 showing how simulated alarm criteria affect the total number of alarm detection events as well as how the simulated alarm criteria affect, for example, false negatives and false positives. The table 3400 is similar to the table 3200 illustrated in FIG. 32, and includes row entries for five different simulated alarm criteria. The table 3400 includes column entries for the number of alarms detected using each simulated alarm criteria. The table 3200 also includes column entries for the change in the number of alarms that were detected using each of the simulated alarm criteria as compared to the number of alarms that were detected using the actual alarm criteria applied at the time of collection of the physiological parameter data.

In addition, the table 3400 includes column entries for the estimated number or percentage of false negatives that previously went undetected but would have been detected using a particular simulated alarm criteria. The table 3400 also includes column entries for the estimated number or percentage of true alarm conditions that were correctly identified using the first alarm criteria but would not have been identified using a particular simulated alarm criteria (i.e., new false negatives resulting from the simulated alarm criteria). These values can be determined or estimated by the reporting module, as described herein. The table 3400 could also include information regarding change in false positives, for example, the number of false positives that were detected

71 by the first alarm criteria that would not have been detected by the simulated alarm criteria, or vice versa.

Again, FIG. 34 illustrates only an example report that could be generated by the reporting module based upon the simulated alarm criteria. It should be understood that such 5 reports could include a wide variety of information to help hospital administrators make a decision as to whether changes to alarm criteria should be made. In addition, such reports can be presented in a wide variety of formats, including tables, charts, graphs, lists, spreadsheets, etc.

In addition to simulating alarm criteria, as described herein, the reporting module can also simulate the effect of other configuration changes in the bedside patient monitoring devices and/or a central patient monitoring station. For example, the reporting module can simulate the effect of 15 different alarm notification delay times. As discussed herein, in some embodiments, when an alarm condition is detected, bedside patient monitors may be configured to wait until a predetermined alarm notification delay time has elapsed before transmitting notification of the alarm event to either 20 a clinician or to a central monitoring station. In addition, the central monitoring station can likewise be configured to wait until a predetermined alarm notification delay time has elapsed before actually transmitting a notification of the detected alarm to a clinician by, for example, a page or other 25 notification method.

These notification delay times can be useful in reducing the frequency of false positive alarm notification events when alarm conditions only transiently persist. Such transient alarm conditions may be triggered by, for example, 30 sudden exertion or emotion. The reporting module can be useful in simulating the effect of differing notification delay times on alarm notification events. This can be useful because, for example, relatively slight modifications to the notification delay times could result in an important reduc- 35 tion in the number of false positives to which clinicians must respond.

FIG. 35 is a flow chart that illustrates a method 3500 for determining the variation in alarm notification events that occurs as a result of varying alarm notification delay times. 40 The method 3500 begins at block 3502 where patients are monitored for physiological parameter alarm events, as described herein.

The method 3500 proceeds to block 3504 where alarm notification events are identified based upon a first alarm 45 notification delay time. For example, an alarm notification event may be a notification by a bedside patient monitor to a central monitoring station of an alarm condition. In this case, the first alarm notification delay time could be measured as the elapsed time between when an alarm condition 50 was detected at the bedside monitor and when notification of the alarm was sent to the central monitoring station. In addition, an alarm notification event may be a notification from a patient monitoring device to a clinician of an alarm condition. In this case, the first alarm notification delay time 55 can be measured as the elapsed time between when an alarm condition was detected and when the clinician was notified.

At the initial time of monitoring, an algorithm, or algorithms, may be applied to the raw physiological signals, processed physiological signals, and/or computed physi- 60 ological parameter values for detecting whether an alarm condition has persisted for the duration of the first alarm notification delay time. This can be done by, for example, each bedside patient monitor for each patient in the patient care domain. If an alarm condition persists for the duration 65 of the first alarm notification delay time, then an alarm notification event can be recognized.

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At block 3506, physiological parameter data is collected and stored at, for example, a central repository (e.g., the round-robin database 722), as described herein. At block 3508, the physiological parameter data is re-analyzed by, for example, the reporting module using a second alarm notification delay time that is different from the first alarm notification delay time. If, for example, the first alarm notification delay time used by the patient monitoring device at block 3504 were 5 sec., the physiological parameter data could be re-analyzed using an alarm notification delay time of, for example, 6 sec., or 7 sec., etc. Shorter delay times could also be simulated.

In some cases, if the alarm condition is only transient in nature, a relatively small lengthening of the alarm notification delay time could result in the alarm condition ceasing before an alarm notification event is generated. In this way, adjustment of the alarm notification delay time can potentially safely reduce the number of alarm notification events to which clinicians must respond. This can in turn increase the effectiveness of patient care by allowing clinicians to focus their time on attending to alarm events that are non-transient. Of course, any change to alarm notification delay times should generally be approved by hospital administrators or other responsible personnel to ensure that, for example, increases in the alarm notification delay times do not unacceptably put patients at risk by increasing the amount of elapsed time between a detected alarm and the arrival of a clinician.

The analysis of the previously-collected physiological parameter data by the reporting module can be used to simulate the effect of a new alarm notification delay time in a riskless manner since patients can still be monitored at, for example, blocks 3502, 3504 using a delay time that has already been accepted and validated. This ability to simulate the effect that new alarm notification delay times would have, without necessarily actually implementing them, is advantageous to hospitals and other patient care facilities as a means of adjusting alarm notification delay times to be specifically adapted for that particular hospital or patient care facility. As described herein with respect to alarm criteria, a change in the alarm notification delay times may result in significantly fewer alarm notification events without necessarily increasing the risk to patients.

At block 3510, the reporting module can analyze differences between clinician notification events that are detected using the first alarm notification delay time as compared to those that are detected using the second alarm notification delay time. For example, the reporting module may determine whether the total number of alarm notification events decreases or increases, and by how much, in response to a change in the alarm notification delay time. This information can be presented to hospital administrators in the form of tables, charts, spreadsheets, etc. to assist them in determining whether a change in the alarm notification delay times implemented by the patient monitoring devices would be advantageous.

Clinician response time data can also be collected and stored for analysis by the reporting module. Clinician response time can be measured as, for example, the elapsed time between when a clinician is notified of an alarm condition and when the clinician arrives at the patient's room to shutoff the alarm and check the patient's status. This elapsed time can be measured by, for example, the bedside patient monitoring devices and transmitted to the central repository of data. Clinician response times can be stored for each clinician and/or for a group of clinicians as a whole. As a result, the reporting module can output information regard-

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ing, for example, the maximum, minimum, and average response times for each clinician, and/or for a group of clinicians as a whole. This data may be useful to hospital administrators as an indicator of the performance of an individual clinician, or a group of clinicians, in responding to monitoring alarms in a prompt manner.

Display Features

FIGS. **36**A-B illustrate displays having layout zones including zones for parameters **3610**, a plethysmograph **3620**, a prompt window **3630**, patient information **3640**, monitor settings **3650**, monitor status **3660**, user profiles **3670**, a parameter well **3680**, pulse-to-pulse signal quality bars **3690** and soft key menus **3695**. Advantageously, each zone dynamically scales information for readability of parameters most important to the proximate user. Also, the prompt window **3630** utilizes layered messaging that temporarily overwrites a less critical portion of the display. Further, the parameter well **3680** contains parameters that the proximate user has chosen to minimize until they alarm. These and other display efficiency features are described below.

FIGS. 37A-F illustrate displays that vary layouts and font sizes according to the number of installed parameters. Horizontal and vertical display formats are shown for displaying eight parameters (FIG. 37A); seven parameters (FIG. 37B); six parameters (FIG. 37C); five parameters (FIG. 37D); four parameters (FIG. 37E); and three parameters (FIG. 37F). Advantageously, font size increases with fewer installed parameters. Further, parameter layout varies according to the number of installed parameters. Also, the plethysmograph display increases in size with few installed parameters. In addition, font size of text information scales according to the amount of information displayed, e.g. patient name is displayed in a scales according to the amount of information displayed, e.g. patient name is displayed in a scales.

FIGS. **38**A-B illustrate displays **3800** having parameter wells **3810**. In particular, parameter values are displayed in either a main display portion or in a parameter well. Through a menu selection or by user profile activated by user proximity, a parameter is minimized to the parameter well. Advantageously, one or more parameters in the parameter well are displayed in a relatively small font. However, when a minimized parameter alarms, it is removed from the parameter well and return in a relatively larger font to the 45 main display.

FIGS. 39A-B illustrate enlarged parameter displays 3900. 3901 that increase the font size of alarming parameters. In normal conditions, all parameters are display in a same sized font. When an alarm occurs, the violating parameter's actual 50 value and limit values are displayed in a larger font and also blink to draw attention to the violation. In another embodiment, where all parameters are displayed at or near the maximum-sized font, then the alarming parameter will increase only slightly in size while all other parameters are 55 reduced in size. Thus, the effect is an appearance that the alarming parameter is enlarged. In an embodiment, if either a single parameter alarms (FIG. 39A) or all parameters alarm (FIG. 39B), the background color also blinks at the same frequency so as to contrast with the blinking font, such 60 as between a red background color and a soft red background color.

FIGS. **40-43** illustrate additional display embodiments having various advantageous features. FIGS. **40**A-B illustrate trend displays **4000** having colored alarm zones **4010** 65 so that a user can readily identify the historical severity of a patient condition that triggers an alarm. FIG. **41** illustrate

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displays that invert arrow keys to match the cursor. FIGS. **43**A-B illustrate trend displays and corresponding set-up screens

FIG. 42 illustrates a display having user-selectable jump-screens. In particular, through a menu option choice, a user can choose one of multiple jump screens, such as the seven choices shown, that they can access from the home page. In an embodiment, the default behavior for the button is the Trend-Toggle button 4231. Other buttons are Alarm Limits 4232, Compressed Waveform View or PI & PVI trend overlay 4233, Mode Sensitivity 4234, Patient Assess 4235, Parameter Detail Toggle 4236 and User Profile Login 4237.

Information and signals described herein can be represented using any of a variety of different technologies and techniques. For example, data, instructions, commands, information, signals, bits, symbols, and chips that can be referenced throughout the above description can be represented by voltages, currents, electromagnetic waves, magnetic fields or particles, optical fields or particles, or any combination thereof.

The various illustrative logical blocks, modules, circuits, and algorithm steps described in connection with the embodiments disclosed herein may be implemented as electronic hardware, computer software, or combinations of both. To clearly illustrate this interchangeability of hardware and software, various illustrative components, blocks, modules, circuits, and steps have been described above generally in terms of their functionality. Whether such functionality is implemented as hardware or software depends upon the particular application and design constraints imposed on the overall system. Skilled artisans can implement the described functionality in varying ways for each particular application, but such implementation decisions should not be interpreted as causing a departure from the scope of the present invention

Depending on the embodiment, certain acts, events, or functions of any of the methods described herein can be performed in a different sequence, may be added, merged, or left out all together (e.g., not all described acts or events are necessary for the practice of the method). Moreover, in certain embodiments, acts or events may be performed concurrently, e.g., through multi-threaded processing, interrupt processing, or multiple processors, rather than sequentially.

The various illustrative logical blocks, modules, and circuits described in connection with the embodiments disclosed herein can be implemented or performed with a general purpose processor, a digital signal processor (DSP), an application specific integrated circuit (ASIC), a field programmable gate array (FPGA) or other programmable logic device, discrete gate or transistor logic, discrete hardware components, or any combination thereof designed to perform the functions described herein. A general purpose processor can be a microprocessor, conventional processor, controller, microcontroller, state machine, etc. A processor can also be implemented as a combination of computing devices, e.g., a combination of a DSP and a microprocessor, a plurality of microprocessors, one or more microprocessors in conjunction with a DSP core, or any other such configuration. In addition, the term "processing" is a broad term meant to encompass several meanings including, for example, implementing program code, executing instructions, manipulating signals, filtering, performing arithmetic operations, and the like.

The steps of a method or algorithm described in connection with the embodiments disclosed herein can be embodied directly in hardware, in a software module executed by

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a processor, or in a combination of the two. A software module can reside in RAM memory, flash memory, ROM memory, EPROM memory, EEPROM memory, registers, hard disk, a removable disk, a CD-ROM, a DVD, or any other form of storage medium known in the art. A storage 5 medium is coupled to the processor such that the processor can read information from, and write information to, the storage medium. In the alternative, the storage medium may be integral to the processor. The processor and the storage medium can reside in an ASIC. The ASIC can reside in a user terminal. In the alternative, the processor and the storage medium can reside as discrete components in a user terminal.

The modules can include, but are not limited to, any of the following: software or hardware components such as soft- 15 ware object-oriented software components, class components and task components, processes, methods, functions, attributes, procedures, subroutines, segments of program code, drivers, firmware, microcode, circuitry, data, databases, data structures, tables, arrays, or variables.

In addition, although this invention has been disclosed in the context of certain preferred embodiments, it should be understood that certain advantages, features and aspects of the systems, devices, and methods may be realized in a variety of other embodiments. Additionally, it is contem- 25 plated that various aspects and features described herein can be practiced separately, combined together, or substituted for one another, and that a variety of combination and subcombinations of the features and aspects can be made and still fall within the scope of the invention. Furthermore, 30 the systems and devices described above need not include all of the modules and functions described in the preferred embodiments.

What is claimed is:

- 1. A system configured to reduce a frequency of alarms 35 from a physiological monitoring system, the system comprising:
 - a physiological sensor configured to detect signals representative of a physiological condition of a patient;
 - one or more processors configured to receive the detected 40 signals and determine a physiological parameter of the patient, the one or more processors further configured to detect an alarm condition for the physiological parameter and delay a notification of the alarm condition until the alarm condition persists for a predeter- 45 mined alarm notification delay time, wherein said one or more processors are configured to provide a notification of the alarm condition responsive to the alarm condition persisting through the alarm notification delay time, the one or more processors being associated 50 with a care unit; and
 - a reporting module configured to simulate, using measurements obtained from the care unit, different alarm notification delay times to determine whether any of the different alarm notification delay times would have 55 resulted in an alarm notification event, the alarm notification event for each different alarm notification delay time indicating that an alarm condition persisted for at

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- least that alarm notification delay time, and to provide an indicator of the effect of a change in alarm notification delay time on frequency of alarm notification events; wherein the indicator is indicative of a change in the alarm notification delay time that is effective to reduce the frequency of transient or false alarms and wherein the indicator is configured to be used to program one or more physiological monitoring systems with alarm notification delay times.
- 2. The system of claim 1, wherein delay of the notification comprises a delay in transmitting the notification to a central patient monitoring station.
- 3. The system of claim 1, wherein delay of the notification comprises a delay in transmitting the notification to a clinician.
- 4. The system of claim 3, wherein transmitting the notification to a clinician comprising transmitting to a cell phone
- 5. A method of reducing a frequency of alarms, the method comprising:
 - collecting signals representative of a physiological condition of a patient;
 - determining a physiological parameter of the patient;
 - detecting an alarm condition for the physiological param-
 - delaying notification of the alarm condition until the alarm condition persists for a predetermined alarm notification delay time;
 - providing a notification of the alarm condition responsive to the alarm condition persisting through the alarm notification delay time;
 - simulating, using measurements obtained from a care unit, different alarm notification delay times to determine whether any of the different alarm notification delay times would have resulted in an alarm notification event, the alarm notification event for each different alarm notification delay time indicating that an alarm condition persisted for at least that alarm notification delay time; and
 - providing an indicator of the effect of a change in alarm notification delay time on frequency of alarm notification events; wherein the indicator is indicative of a change in the alarm notification delay time that is effective to reduce the frequency of transient or false alarms and wherein the indicator is configured to be used to program one or more physiological monitoring systems with alarm notification delay times.
- 6. The method of claim 5, wherein the delaying of the notification comprises delaying transmission of the notification to a central patient monitoring station.
- 7. The method of claim 5, wherein the delaying of the notification comprises delaying transmission of the notification to a clinician.
- 8. The method of claim 7, wherein transmission of the notification to the clinician further comprises transmission to a cell phone or pager.

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(54) ALARM SUSPEND SYSTEM

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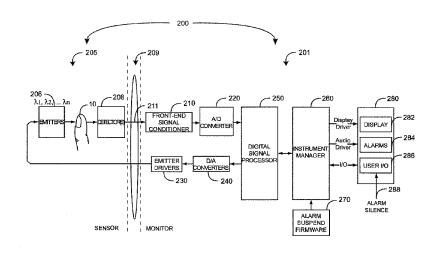
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(57) ABSTRACT

An alarm suspend system utilizes an alarm trigger responsive to physiological parameters and corresponding limits on those parameters. The parameters are associated with both fast and slow treatment times corresponding to length of time it takes for a person to respond to medical treatment for out-of-limit parameter measurements. Audible and visual alarms respond to the alarm trigger. An alarm silence button is pressed to silence the audible alarm for a predetermined suspend time. The audible alarm is activated after the suspend time has lapsed. Longer suspend times are associated with slow treatment parameters and shorter suspend times are associated with fast treatment parameters.

25 Claims, 5 Drawing Sheets



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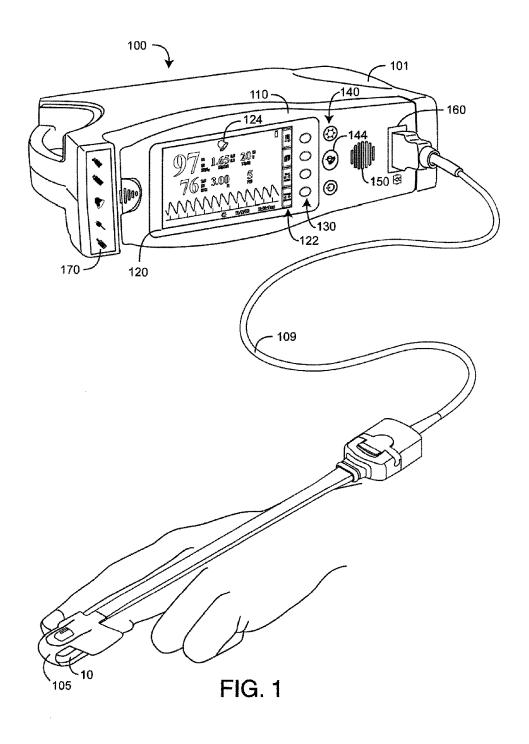
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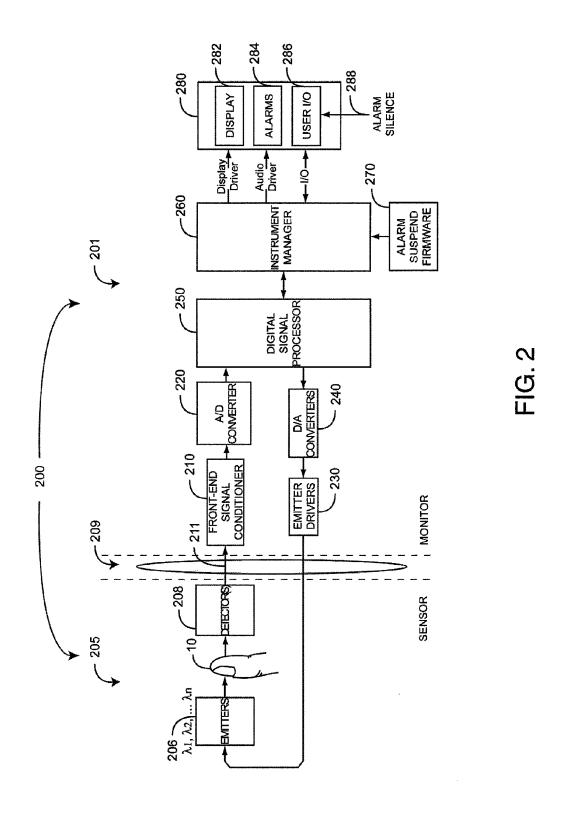
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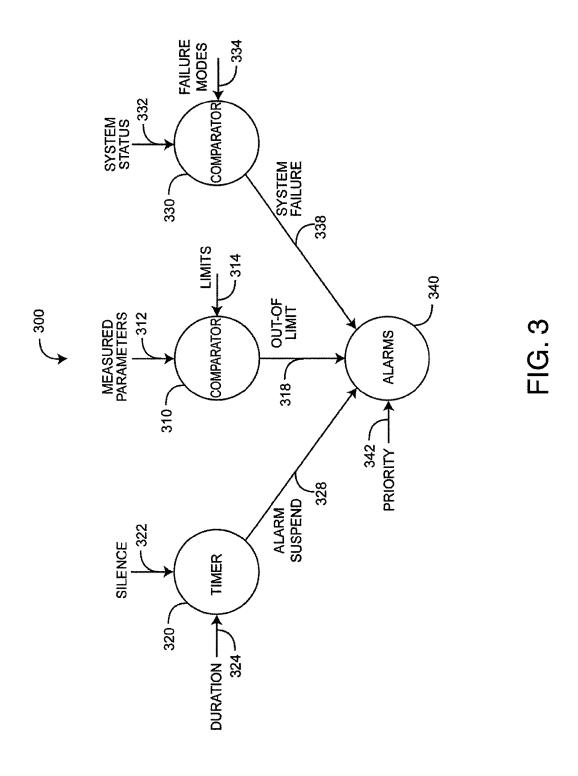
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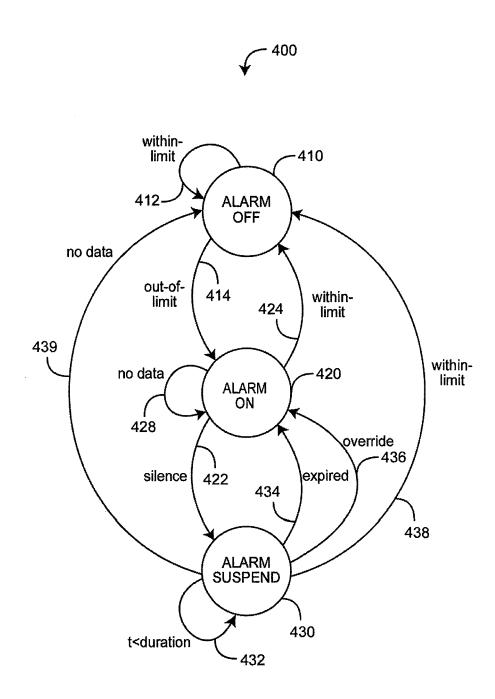


FIG. 4

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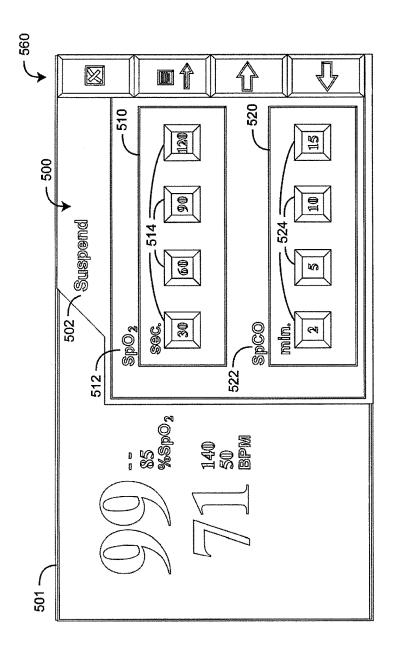


FIG. 5

1 ALARM SUSPEND SYSTEM

Matter enclosed in heavy brackets [] appears in the original patent but forms no part of this reissue specification; matter printed in italics indicates the additions made by reissue; a claim printed with strikethrough indicates that the claim was canceled, disclaimed, or held invalid by a prior post-patent action or proceeding.

CROSS-REFERENCE TO RELATED APPLICATIONS

This [application] is an application for reissue of U.S. Pat. No. 9,153,121, issued on Oct. 6, 2015 and titled "Alarm 15 Suspend System," which is a continuation of U.S. patent application Ser. No. 14/036,496, filed Sep. 25, 2013 and titled "Alarm Suspend System," which is a continuation of U.S. patent application Ser. No. 13/476,725, filed May 21, 2012 and titled "Alarm Suspend System," which is a con- 20 tinuation of U.S. patent application Ser. No. 12/510,982 filed Jul. 28, 2009 and titled "Alarm Suspend System," which claims priority benefit under 35 U.S.C. § 119(e) to U.S. Provisional Patent Application Ser. No. 61/084,615, filed Jul. 29, 2008, titled "Alarm Management System[."]; "more 25 than one reissue application has been filed for the reissue of U.S. Pat. No. 9,153,121, including U.S. patent application Ser. No. 15/583,922 (the present application), U.S. patent application Ser. No. 15/583,948, and U.S. patent application Ser. No. 15/583,935. All of the above-referenced applica- 30 tions are hereby incorporated by reference herein in their entireties.

BACKGROUND

Pulse oximetry for measuring constituents of circulating blood has achieved acceptance in a wide variety of medical applications, including surgical wards, intensive care and neonatal units, general wards, home care, physical training, and virtually all types of monitoring scenarios. A pulse 40 oximeter generally includes a two-wavelength optical sensor applied to a patient, a monitor for processing sensor signals and displaying results and a patient cable electrically interconnecting the sensor and the monitor. The monitor typically provides a numerical readout of physiological parameters 45 such as oxygen saturation (SpO₂) and pulse rate (PR). Advanced physiological monitors utilize multiple wavelength sensors and enhanced measurement capabilities to provide readouts of additional parameters, such as carboxyhemoglobin (HbCO), methemoglobin (HbMet) and total 50 hemoglobin (Hbt).

Pulse oximeters capable of reading through motion induced noise are disclosed in at least U.S. Pat. Nos. 6,770,028, 6,658,276, 6,650,917, 6,157,850, 6,002,952, 5,769,785 and 5,758,644; low noise pulse oximetry sensors 55 are disclosed in at least U.S. Pat. Nos. 6,088,607 and 5,782,757; all of which are assigned to Masimo Corporation, Irvine, Calif. ("Masimo") and are incorporated by reference herein.

Physiological monitors and corresponding multiple wavelength optical sensors are described in at least U.S. patent application Ser. No. 11/367,013, filed Mar. 1, 2006 and titled Multiple Wavelength Sensor Emitters and U.S. patent application Ser. No. 11/366,208, filed Mar. 1, 2006 and titled Noninvasive Multi-Parameter Patient Monitor, both 65 assigned to Masimo Laboratories, Irvine, Calif. (Masimo Labs) and both incorporated by reference herein.

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Further, physiological monitoring systems that include low noise optical sensors and pulse oximetry monitors, such as any of LNOP® adhesive or reusable sensors, SofTouchTM sensors, Hi-Fi TraumaTM or BlueTM sensors; and any of Radical®, SatShareTM, Rad-9TM, Rad-5TM, Rad-5TM, Rad-5TM or PPO+TM Masimo SET® pulse oximeters, are all available from Masimo. Physiological monitoring systems including multiple wavelength sensors and corresponding noninvasive blood parameter monitors, such as RainbowTM adhesive and reusable sensors and RAD-57TM and Radical-7TM monitors for measuring SpO₂, pulse rate (PR), perfusion index (PI), pleth variability index (PVI), signal quality, HbCO and HbMet among other parameters are also available from Masimo.

SUMMARY OF THE INVENTION

Monitor alarms are triggered by out-of-limit parameters and system failures, the latter including monitor or sensor failures or improper sensor placement, to name a few. Alarms can be visual, audible or both. Alarms can also have different levels of priority, which are reflected in the type of visual and audible alarms. In an embodiment, parameters exceeding limits such as low SpO₂, high HbCO, high HbMet and low and high BPM trigger high priority alarms. System failures due to sensor off, no sensor or defective sensor also trigger high priority alarms. Parameters exceeding limits such as high SpO₂, low and high PI, low and high PVI, for example, trigger medium priority alarms. Parameters exceeding limits such as low HbCO and low HbMet along with a system low battery indication are examples of low priority alarms.

An audible alarm may be temporarily suspended by pressing an alarm silence button so as to prevent unnecessary disturbance to the patient and distraction of the caregiver. During alarm suspension, visual alarms remain active. If an alarm condition persists after a predetermined alarm suspend period, the audible alarm resumes. The alarm suspend period is typically long enough to give a caregiver sufficient time to intervene with appropriate patient treatment yet short enough to ensure that patient health is not endangered if intervention is ineffective. For conventional pulse oximetry, an alarm suspend may be, for example, a maximum of 120 seconds.

Alarm suspension on advanced blood parameter monitors is problematic. With conventional pulse oximetry, treatment for abnormal parameter measurements can be quickly applied and a patient response is typically fast. For example, a treatment for low oxygen saturation is the application of an oxygen mask or an increase in oxygen flow. By contrast, the duration of treatment for parameters measured by advanced monitors is highly dependent on the alarm-triggering parameter. For example, the treatment for high methemoglobin is the injection of methylene blue, and the patient response to such an injection is slow. When patient treatment time exceeds the maximum alarm suspend period, an audible alarm will constantly reactivate. Thus, a single alarm suspend duration for all parameters is inadequate to cope with the many different types of parameters measured by advanced monitors.

One aspect of an alarm suspend system for silencing the alarms is an alarm trigger responsive to any of various parameters and predetermined limits corresponding to the parameters, where the parameters are partitioned according to treatment time, i.e. the relative length of time it takes for a person to respond to medical treatment for a parameter measurement outside of the predetermined limits. An

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audible alarm is responsive to the alarm trigger. An alarm silence button is actuated so as to suspend the audible alarm. A timer tracks the duration of the suspended alarm and is initiated by actuation of an alarm silence button. The timer retriggers the audible alarm after the timed duration has 5 lapsed/expired. In an embodiment, a long duration suspend time is associated with slow treatment parameters and a short duration suspend time is associated with fast treatment parameters. Fast treatment parameters may include, for example, parameters relating to normal blood hemoglobin 10 constituents and slow treatment parameters may include parameters relating to abnormal blood hemoglobin constitu-

In various embodiments, a short duration suspend time is less than or equal to about two minutes and a long duration 15 measurement system utilizing an alarm suspend system; suspended time is greater than about two minutes. A default duration associated with the fast treatment parameters is about two minutes and a default duration associated with the slow treatment parameters is about fifteen minutes. The alarm suspend system may also have an alarm suspend 20 override responsive to a predetermined unit change in the parameter triggering a suspended alarm. The override results in reactivation of the suspended alarm. A physiological monitor having an alarm suspend system may also have a pop-up window that appears on the monitor display in 25 response to actuation of the silence button, where the pop-up window presents a choice of alarm suspend durations.

Another aspect of an alarm suspend system is a partition of measured parameters into at least a first group and a second group. An audible alarm is triggered if at least one 30 parameter is outside of predetermined limits. The audible alarm is suspended in response to a silence request. A first duration is associated with the first group and a second duration is associated with the second group. The audible alarm is reactivated after at least one of the first duration and 35 the second duration. The first duration may be set so as to generally correspond to a first range of treatment times for the first group of parameters. Likewise, the second duration may be set so as to generally correspond to a second range of treatment times for the second group of parameters, where 40 the first range of treatment times and the second range of treatment times are non-overlapping.

In various embodiments, suspended audible alarms are overridden if the triggering parameter has greater than a predetermined unit change before the suspended alarm 45 expires according to either the first duration or the second duration. The first and second groups are defined in relation to normal hemoglobin measurements abnormal hemoglobin measurements, respectively. The first duration is set to be less than or equal to two minutes and the second duration is 50 set to be greater than two minutes, with default durations of about two minutes corresponding to the first group and about fifteen minutes corresponding to the second group. In an embodiment, a pop-up window for a monitor display is constructed and the first duration and the second duration are 55 selected from a range of durations presented within the pop-up window.

A further aspect of an alarm suspend system deactivates an audible alarm for one of a short duration and a long duration according to the alarm-triggering parameter. A first 60 group of parameters is associated with the short duration and a second group of parameters is associated with the long duration. The first group and the second group are partitioned according to a fast treatment time and a short treatment time associated with the parameters. An override 65 reactivates the audible alarm if the trigger parameter changes more than a predetermine amount during the cor-

responding duration. In various embodiments, the first group comprises parameters related to the measurement of normal hemoglobin and the second group comprises parameters related to the measurement of abnormal hemoglobin. The long duration is greater than about 120 seconds and the short duration is less than or equal to about 120 seconds. A pop-up window for the display allows selection of the long duration and the short duration in response to the silence button.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of a physiological measurement system utilizing an alarm suspend system;

FIG. 2 is a detailed block diagram of a physiological

FIG. 3 is a flow diagram of an alarm suspend system embodiment;

FIG. 4 is a state diagram of an alarm suspend system embodiment; and

FIG. 5 is an illustration of an alarm suspend pop-up window.

DETAILED DESCRIPTION

FIG. 1 illustrates a physiological measurement system 100 that utilizes an alarm suspend system. The physiological measurement system 100 has a noninvasive sensor 105 attached to a tissue site ${\bf 10}$, a physiological monitor ${\bf 101}$, and an interface cable 109 interconnecting the monitor 101 and the sensor 105. The physiological measurement system 100 may incorporate pulse oximetry in addition to advanced features, such as a multiple wavelength sensor and advanced processes for determining physiological parameters other than or in addition to those of pulse oximetry, such as carboxyhemoglobin, methemoglobin and total hemoglobin, as a few examples.

The monitor 101 has a front panel 110 providing a display 120, touch keys 130, controls 140, a speaker 150, a sensor port 160 and status indicators 170. The display 120 shows parameter readouts, limits and waveforms among other items. The display 120 also has touch key icons 122 that indicate touch key 130 functions. The speaker 150 provides an audible alarm in response to physiological measurements that violate preset conditions, such as an out-of-limit parameter, as well as system failures, such as a low battery condition. The controls 140 include an alarm silence button 144 that is pressed to temporarily suspend out-of-limit parameter alarms and system alarms, such as low battery. The display 120 provides visual alarms, which include a bell-shaped alarm status indicator 124 that illuminates during an alarm condition and parameter readouts 210 and limits 220 that flash when parameters are out-of-limit. Status indicators 170 also provide visual alarms. When there are multiple alarm conditions, the parameter displays 202 indicate parameters with the highest alarm priority. Touch keys 130 and corresponding icons 122 include an alarm menu access button for setting alarm conditions, such as high or low alarm limits for SpO₂, HbCO, HbMet, PR and PI. The alarm silence button 144 is pressed to temporarily suspend audible alarms. Advantageously, an alarm suspend system provides a parameter-dependent variation in the alarm suspend duration, as described below, utilizing a common silence button or other suspend initiator.

FIG. 2 illustrates a physiological measurement system 200 including a physiological monitor 201, a sensor 205 and an interface cable 209. The sensor 205 is attached to a tissue site, such as a finger 10, and includes a plurality of emitters

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206 irradiating the tissue site 10 with multiple wavelengths of light. The sensor 205 also includes one or more detectors 208 capable of detecting the light after attenuation by the tissue site 10. The sensor 205 transmits optical radiation at wavelengths other than or including the red and infrared 5 wavelengths utilized in pulse oximeters. The monitor 201 inputs a corresponding sensor signal 211 and determines the relative concentrations of blood constituents other than or in addition to the "normal" blood hemoglobin constituents $\rm HbO_2$ and $\rm Hb$, including "abnormal" blood hemoglobin 10 constituents $\rm HbC_0$, $\rm HbMet$ and blood related parameters such as fractional oxygen saturation, total hemoglobin and blood glucose to name a few.

As shown in FIG. 2, the monitor 201 has a front-end signal conditioner 210, an A/D converter 220, emitter drivers 230, D/A converters 240 and a digital signal processor ("DSP") 250. In general, the emitter drivers 230 convert digital control signals, via the D/A converters 240, into analog drive signals capable of driving the sensor emitters 206. The front-end signal conditioner 210 converts, via the 20 A/D converter 220, composite analog intensity signal(s) from light sensitive detector(s) 208 into digital data input to the DSP 250. The emitter drivers 230 and front-end signal conditioner 210 communicate with the sensor 205 via the interface cable 209.

Also shown in FIG. 2, the monitor 201 has an instrument manager 260 and a user interface 280. The user interface 280 includes one or more displays 282, alarms 284 and user input/output (I/O) 286. The instrument manager 260 communicates with the DSP 250 to receive parameter data and 30 to present that data on the display 282. The instrument manager 260 may also store and display historical or trending data related to one or more of the measured parameters or combinations of the measured parameters. The instrument manager 260 also controls audible and visual alarms and 35 indicators 284. The instrument manager 260 responds to user-actuated keys and communicates with external devices via various I/O ports 286. Further, the instrument manager 260 executes alarm suspend firmware 270 so as to respond to an alarm silence button press 288, as described in detail 40 with respect to FIGS. 3-4.

FIG. 3 generally illustrates an alarm suspend system 300. Alarm triggers include system failures 338 and out-of-limit parameters 318. Triggered alarms 340 may be audible, visual or both, and may vary according to priority 342. 45 Audible alarms may be generated by a monitor front-panel-mounted speaker 150 (FIG. 1) and may vary in loudness, pitch and sound pattern. Visual alarms may include parameter labels, parameter numerics, symbols and status lights, which can flash and vary in color.

As shown in FIG. 3, measured parameters 312 are compared 310 to default or user-specified limits 314. An out-of-limit condition 318 triggers an alarm 340. An alarm suspend 328 is user-initiated by a silence request 322. This may be a press of a silence button 144 (FIG. 1) on a monitor 55 front panel 110 (FIG. 1). In an embodiment, the alarm suspend 328 silences audible alarms and modifies the display of visual alarms. The alarm suspend 328 is based on a timer 320, which ends the alarm suspend 328 after a predetermined duration 324. The duration 324 may be a 60 function of the out-of-limit parameter 312. In an advantageous embodiment, the duration 324 relates to, or is a function of, the treatment time for the alarm-triggering parameter so as to avoid nuisance alarms while maintaining alarm integrity.

FIG. 4 illustrates an alarm suspend embodiment 400 that operates independently for each measured parameter that

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can trigger an alarm. An alarm is initially off 410. The alarm remains off as long as the parameter is within its set limits 412. If a parameter is measured outside of its set limits 414, an alarm is triggered 420. The alarm may audible, visual or both audible and visual. A user can request to silence the alarm by pressing an alarm silence button 144 (FIG. 1), for example. The silence request 422 suspends the alarm 430 which turns off audible alarms but, in an embodiment, does not deactivate visual alarms. The audible alarm remains suspended 430 for a predetermined duration 432. When the suspend duration has passed, the alarm suspend expires 434 and audible alarms are once again activated 420. The alarm remains on 428 until the triggering parameter is within limits 424 or a user once again requests silence 422. The alarm suspend 430 deactivates if the measured parameter becomes within limits 438, such as when the patient condition improves, or if no physiological data is detected 439, such as no sensor, sensor off, no cable or malfunctioning sensor situations, to name a few. Also, if the measured parameter changes during the alarm suspend 430 by a sufficient outof-limit amount, an override 436 reactivates the audible alarms 420.

In an alarm suspend system embodiment, parameters are classified according to the typical time it takes for medical treatment to transition an out-of-limit measurement to a within-limit measurement. Suspend durations 324 (FIG. 3) are set accordingly. For example, in a two-tier embodiment, relatively slow treatment parameters, such as HbMet, HbCO, Hbt and PVI, are assigned relatively long suspend durations. Similarly, relatively fast treatment parameters, such as SpO2 and PR, are assigned relatively short suspend durations. In an embodiment, the alarm suspend duration is adjustable for each individual parameter, including 2, 5, 10, 15, 20, 25 and 30 minutes for slow treatment parameters, with a default of 15 minutes; and 30, 60, 90 and 120 seconds for fast treatment parameters, with a default of 120 seconds. These alarm features are only active when alarm limits have been set. Other alarm features apply to both slow treatment and fast treatment parameters. For example, an alarm delay of 0, 5, 10 or 15 seconds applies to all enabled parameters.

In an embodiment, an override **436** occurs if slow treatment parameters such as HbCO, HbMet or PVI increase or Hbt decreases by a certain unit change during the alarm suspend duration. The unit change is adjustable for each parameter, such as from 1-15 in increments of 1. TABLE 1 shows a default embodiment of override unit changes for these parameters.

TABLE 1

Override Unit Changes for Selected Parameters						
Parameter Unit Change Direction						
HbCO HbMet Hbt PVI	5 2 2 OFF	Increase Increase Decrease Increase				

FIG. 5 illustrates an alarm suspend window 500 that provides a "pop-up" display so that a monitor user may manually enter an alarm suspend duration. The alarm suspend window 500 appears as a portion of a monitor display 501, such as the front panel display 120 (FIG. 1) described above. The pop-up window 500 responds to a suspend request, such as a silence button 144 (FIG. 1) press. The alarm suspend window 500 has a window identifier 502 and one or more parameter subsections 510, 520. Each param-

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eter subsection 510, 520 has a parameter identifier 512, 522 and corresponding suspend duration options 514, 524. In an embodiment, specific suspend times are selected via monitor touch keys 130 (FIG. 1) as guided by corresponding touch key icons 560. Selected suspend times are highlighted or 5 otherwise identified and entered, also via a touch key 130 (FIG. 1). In an alternative embodiment, the monitor display is a touch screen and alarm suspend times are directly entered by a finger press on a specific duration "virtual button" 514, 524. Once one or more suspend durations are 10 entered, the pop-up window 500 disappears from the display 501. The alarm suspend window 500 advantageously allows a user to quickly choose an appropriate alarm suspend duration for the situation at hand, rather than relying on a predetermined or default duration.

An alarm suspend system is described above with respect to alarms triggered by measured parameters and limits associated with those measured parameters. Limits may correspond to levels of a measured parameter, such as a percentage oxygen saturation to name but one example. 20 Limits may also correspond to trends of a measured parameter, such as a rate-of-change of oxygen saturation, for example. Limits may also correspond to patterns in a measured parameter or a comparison of one measured parameter with another measured parameter, as further examples.

An alarm suspend system is described above with respect to a two-tier grouping of parameters, such as slow treatment and fast treatment parameters and alarm suspend durations associated with those groups. Groupings of parameters with respect to alarm suspend durations may be multi-tier, such as 30 slow, medium and fast treatment parameters, to name but one example.

An alarm suspend system has been disclosed in detail in connection with various embodiments. These embodiments are disclosed by way of examples only and are not to limit 35 the scope of the claims that follow. One of ordinary skill in the art will appreciate many variations and modifications.

What is claimed is:

- 1. A physiological measurement system comprising:
- a *noninvasive* physiological sensor [including: a plurality 40 of light emitting diodes] configured to [transmit wavelengths of light onto a tissue site of a patient; and at least one detector configured to measure an indication of the wavelengths of light after attenuation by tissue of the patient and be positioned on a patient and output 45 a signal responsive [of the attenuated light] to a physiological condition of the patient; and
- one or more processors in communication with the *non-invasive* physiological sensor, the one or more processors configured to *electronically*:
 - process the signal to determine a measurement of a physiological parameter based at least in part upon the signal;
 - determine that an alarm should be activated in response to the measurement of the physiological 55 parameter satisfying an alarm activation threshold;
 - [receive, from a user,] determine that an [indication of] alarm suspension should be initiated for a parameter-specific alarm suspension period of time corresponding to the physiological parameter, the parameter-specific alarm suspension period of time being [selected from] one of at least a plurality of parameter-specific alarm suspension periods of time, the parameter-specific alarm suspension period of time being different from at least one other parameter-specific alarm suspension period of time corresponding to at least one other physiological parameter for

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- which the one or more processors are configured to determine at least one measurement; [activate an alarm in response to determining that an alarm activation threshold has been satisfied by the physiological parameter measurement; receive an alarm suspension indication; and in response to receiving the alarm suspension indication,]
- suspend the alarm for the [indicated] parameter-specific alarm suspension period of time; and
- activate the alarm when the measurement of the physiological parameter satisfies the alarm activation threshold after the parameter-specific alarm suspension period of time has passed.
- 2. The physiological measurement system of claim 1, wherein the one or more processors are further configured to:
 - provide a user interface to the user including at least a plurality of user-selectable elements, each of the [selectable] plurality of user-selectable elements corresponding to one of the plurality of parameter-specific alarm suspension periods of time.
- 3. The physiological measurement system of claim 2, wherein providing the user interface further includes:
 - constructing a pop-up window for a display; and displaying the plurality of user-selectable elements in the pop-up window.
- 4. The physiological measurement system of claim 3, wherein the plurality of user-selectable elements are configured to allow a user to select a specific one of the plurality of parameter-specific alarm suspension periods of time.
- 5. The physiological measurement system of claim 4, wherein [the] a selected parameter-specific alarm suspension period of time is selected by selection of one of the plurality of user-selectable elements.
- **6**. The physiological measurement system of claim **1**, wherein the one or more processors are further configured to:
 - associate [the] a selected parameter-specific alarm suspension period of time [is] with the physiological parameter.
- 7. The physiological measurement system of claim 6, wherein the selected parameter-specific period of time is stored in a memory device in communication with the one or more processors.
- **8**. The physiological measurement system of claim **1**, wherein the one or more processors are further configured to:
 - process the signal to determine a measurement of a second physiological parameter [measurement] based at least in part upon the signal;
 - determine that a second alarm should be activated in response to the measurement of the second physiological parameter satisfying a second alarm activation threshold;
 - [receive, from the user,] determine that a second [indication of] alarm suspension should be initiated for a second parameter-specific alarm suspension period of time corresponding to the second physiological parameter, the second parameter-specific alarm suspension period of time being [selected from] one of a second plurality of parameter-specific alarm suspension periods of time; [activate a second alarm in response to determining a second alarm activation threshold has been satisfied by the second physiological parameter measurement; and in response to receiving the alarm suspension indication,]

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- suspend the second alarm for the [indicated] second parameter-specific alarm suspension period of time;
- activate the second alarm when the measurement of the second physiological parameter satisfies the second 5 alarm activation threshold after the second parameter-specific alarm suspension period of time has passed.
- **9.** The physiological measurement system of claim **8**, wherein the one or more processors are further configured to:
 - provide a user interface to the user including at least a first plurality of user-selectable elements and a second plurality of user-selectable elements, wherein each of the first plurality of user-selectable elements corresponds to one of the plurality of parameter-specific alarm 15 suspension periods of time, and each of the second plurality of user-selectable element corresponds to one of the second plurality of parameter-specific alarm suspension periods of time.
- 10. The physiological measurement system of claim 9, 20 wherein the one or more processors are further configured to:

construct a pop-up window for a display; and display both the first and second plurality of user-selectable elements in the pop-up window.

- 11. The physiological measurement system of claim 10, wherein [the] a selected *first* parameter-specific alarm suspension period of time is selected by selection of one of the first plurality of user-selectable elements, and [the] a selected second parameter-specific alarm suspension period 30 of time is selected by selection of one of the second plurality of user-selectable elements.
- 12. The physiological measurement system of claim 11, wherein the at least one of the [first] plurality of parameter-specific alarm suspension periods of time is different from 35 any of the second plurality of parameter-specific alarm suspension periods of time.
- 13. [An] A method of electronically delaying an alarm while an electronically calculated measurement of a physiological parameter satisfies an alarm activation threshold, 40 the measurement of the physiological parameter responsive to a signal from a noninvasive sensor positioned at a monitored patient, the method comprising:
 - [measuring] electronically processing a signal from a noninvasive sensor to determine a first measurement of 45 a first physiological parameter and a second measurement of a second physiological parameter using a patient monitoring device, the patient monitoring device including a processor and a memory device [configured to store]; 50
 - electronically storing, in the memory device, a first parameter-specific alarm suspension period of time corresponding to the first physiological parameter and a second parameter-specific alarm suspension period of time corresponding to the second physiological parameter, the first parameter-specific alarm suspension period of time being different from the second parameter-specific alarm suspension period of time;
 - electronically determining when the first measurement of the first physiological parameter satisfies a first alarm 60 activation threshold;
 - [receiving, from a user, an indication of a] electronically determining that a first alarm suspension should be initiated for the first parameter-specific alarm suspension period of time [corresponding to the physiological 65 parameter, the parameter-specific alarm suspension period of time being selected from a plurality of

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- parameter-specific alarm suspension period periods of time, the parameter-specific alarm suspension period of time being different from at least one other parameter-specific alarm suspension period of time corresponding to at least one other physiological parameter; activating an alarm in response to determining an alarm activation threshold has been satisfied by the physiological parameter measurement; receiving an alarm suspension indication];
- [and in response to receiving the alarm suspension indication,] electronically suspending [the] a first alarm for the first physiological parameter for the [indicated] first parameter-specific alarm suspension period of time; and
- electronically activating the first alarm when the first measurement of the first physiological parameter satisfies the first alarm activation threshold subsequent to the first parameter-specific alarm suspension period of time passing.
- 14. The method of claim 13, wherein the *first* alarm includes an audible component and a visual component, and wherein suspending the *first* alarm comprises suspending the audible component and not suspending the visual component.
- 15. The method of claim 13 further comprising: providing a user interface to the user including at least a plurality of user-selectable elements, each of the [selectable] plurality of user-selectable elements corresponding to one of [the] a plurality of parameter-specific alarm suspension periods of time,
- wherein the plurality of parameter-specific alarm suspension periods of time comprise the first parameterspecific alarm suspension period of time.
- 16. The method of claim 15 further comprising: constructing a pop-up window for a display; and displaying the plurality of user-selectable elements in the pop-up window.
- 17. The method of claim 16, wherein [the] a selected parameter-specific alarm suspension period of time is selected by selection of one of the plurality of user-selectable elements.
 - 18. A physiological measurement system comprising: a *noninvasive* physiological sensor [means for outputting] *configured to output* a signal responsive to [a noninvasive measurement of attenuated light transmitted through a tissue site] *a physiological condition* of a
 - a memory configured to store a first alarm activation threshold; and
 - [a processing means] one or more processors in communication with the noninvasive physiological sensor [means] and configured to:
 - process the signal to determine a first measurement of [a] the first measured physiological parameter based at least in part upon the signal;
 - [receive, from a user, an indication of a] determine that a first alarm suspension should be initiated for a first parameter-specific alarm suspension period of time [corresponding to the physiological parameter], the first parameter-specific alarm suspension period of time corresponding to the first measured physiological parameter and being [selected from a plurality of parameter-specific alarm suspension periods of time, the parameter-specific alarm suspension period of time being] different from [at least one other] a second parameter-specific alarm suspension period of time corresponding to [at least one other] a second

patient:

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measured physiological parameter for which the one or more processors are configured to determine a second measurement;

[activate an alarm in response to determining an] determine that the first measurement satisfies the first 5 alarm activation threshold [has been satisfied by the physiological parameter measurement; receive an alarm suspension indication]; and

[in response to receiving the alarm suspension indication,] suspend [the] activation of a first alarm for the 10 [indicated] first parameter-specific alarm suspension period of time and then activate the first alarm.

19. The physiological measurement system of claim 18, wherein the [processing means is] one or more processors are further configured to:

process the signal to determine [a] the second [physiological parameter] measurement based at least in part upon the signal;

[receive, from the user,] determine that a second [indication of a] alarm suspension should be initiated for the 20 second parameter-specific alarm suspension period of time [corresponding to the second physiological parameter, the second parameter-specific alarm suspension period of time being selected from a second plurality of parameter-specific alarm suspension periods of time];

[activate a second alarm in response to determining a] determine that the second measurement satisfies a second alarm activation threshold [has been satisfied by the second physiological parameter measurement]; and 30

[in response to receiving the alarm suspension indication,] suspend *activation of* the second alarm for the [indicated] second parameter-specific alarm suspension period of time *and then activate the second alarm*.

20. The physiological measurement system of claim **19**, 35 wherein the [processing means is] *one or more processors are* further configured to:

provide a user interface to the user including at least a first plurality of user-selectable elements and a second plu-

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rality of user-selectable elements, wherein each of the first plurality of user-selectable elements corresponds to one of [the] a first plurality of parameter-specific alarm suspension periods of time, and each of the second plurality of user-selectable [element] elements corresponds to one of [the] a second plurality of parameter-specific alarm suspension periods of time,

wherein the first plurality of parameter-specific alarm suspension periods of time comprise the first parameter-specific alarm suspension period of time, and the second plurality of parameter-specific alarm suspension periods of time comprise the second parameterspecific alarm suspension period of time.

21. The physiological measurement system of claim 20, wherein [the] a selected first parameter-specific alarm suspension period of time is selected by selection of one of the first plurality of user-selectable elements, and [the] a selected second parameter-specific alarm suspension period of time is selected by selection of one of the second plurality of user-selectable elements.

22. The physiological measurement system of claim 21, wherein at least one of the first plurality of parameter-specific alarm suspension periods of time is different from any of the second plurality of parameter-specific alarm suspension periods of time.

23. The physiological measurement system of claim 1, wherein the alarm comprises an audible alarm.

24. The physiological measurement system of claim 1, wherein the one or more processors are further configured to output a visual indicator with modification for the parameter-specific alarm suspension period of time and then output the visual indicator without modification.

25. The physiological measurement system of claim 1, wherein the physiological parameter is indicative of the physiological condition of a circulatory system of the patient.

* * * * *

Protective Order

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

APPLE INC.,)
Plaintiff,))) C.A. No. 22-1377-MN-JLH
V.)) JURY TRIAL DEMANDED
MASIMO CORPORATION and SOUND UNITED, LLC,))
Defendants.)
MASIMO CORPORATION,	<u>)</u>
Counter-Claimant,)
V.)
APPLE INC.,)
Counter-Defendant.)
APPLE INC.,)
Plaintiff,)
v.) C.A. No. 22-1378-MN-JLH
MASIMO CORPORATION and SOUND UNITED, LLC,) JURY TRIAL DEMANDED)
Defendants.)
MASIMO CORPORATION and CERCACOR LABORATORIES, INC.,)
Counter-Claimants,)
v.)
APPLE INC.,)
Counter-Defendant.)

AGREED PROTECTIVE ORDER REGARDING THE DISCLOSURE AND USE OF DISCOVERY MATERIAL

Plaintiff and Counter-Defendant Apple Inc. ("Plaintiff"), Defendants and Counter-Claimants Masimo Corporation and Sound United, LLC and Counter-Claimant Cercacor Laboratories, Inc. (together, "Masimo") anticipate that documents, testimony, or information containing or reflecting confidential, proprietary, trade secret, and/or commercially sensitive information are likely to be disclosed or produced during the course of discovery, initial disclosures, and supplemental disclosures in these cases and request that the Court enter this Order setting forth the conditions for treating, obtaining, and using such information.

Pursuant to Rule 26(c) of the Federal Rules of Civil Procedure, the Court finds good cause for the following Agreed Protective Order Regarding the Disclosure and Use of Discovery Material ("Order" or "Protective Order").

1. PURPOSES AND LIMITATIONS

- (a) Protected Material designated under the terms of this Protective Order shall be used by a Receiving Party solely for these cases, and shall not be used directly or indirectly for any other purpose whatsoever.
- (b) The Parties acknowledge that this Order does not confer blanket protections on all disclosures during discovery, or in the course of making initial or supplemental disclosures under Rule 26(a). Designations under this Order shall be made with care and shall not be made absent a good faith belief that the designated material satisfies the criteria set forth below. If it comes to a Producing Party's attention that designated material does not qualify for protection at all, or does not qualify for the level of protection initially asserted, the Producing Party must promptly notify all other Parties that it is withdrawing or changing the designation.

(c) Other Proceedings. By entering this order and limiting the disclosure of information in these cases, the Court does not intend to preclude another court from finding that information may be relevant and subject to disclosure in another case. Any person or party subject to this order who becomes subject to a request or motion that would require disclosure of another party's information designated "CONFIDENTIAL," "CONFIDENTIAL - ATTORNEYS' EYES ONLY," or "CONFIDENTIAL - OUTSIDE ATTORNEYS' EYES ONLY - SOURCE CODE," pursuant to this Order shall promptly notify that party of the request or motion so that the party may have an opportunity to appear and be heard on whether that information should be disclosed.

2. **DEFINITIONS**

- (a) "Affiliate" means any corporation, company, or other business entity over which a Party has the power to direct or cause the direction of the management, policies, or legal actions through: (1) at least 50% ownership of voting securities; or (2) contract; or (3) other means.
- (b) "Discovery Material" means all items or information, including from any non-party, regardless of the medium or manner generated, stored, or maintained (including, among other things, testimony, transcripts, or tangible things) that are produced, disclosed, or generated in connection with discovery or Rule 26(a) disclosures in these cases.
- (c) "Outside Counsel" means (i) outside counsel who appear on the pleadings as counsel for a Party and (ii) partners, associates, and staff of such counsel to whom it is reasonably necessary to disclose the information for this litigation.
- (d) "Patents-in-suit" means U.S. Patent Nos. D735,131, D883,279, D947,842, D962,936, 10,076,257, 10,627,783, 10,942,491, 10,987,054, 11,106,352, 11,474,483, 10,912,501, 10,912,502, 10,945,648, 10,687,743, 10,687,745, 10,722,159, 7,761,127, 8,190,223, 10,736,507,

and 10,984,911 and any other patent asserted in these cases, as well as any related patents, patent applications, provisional patent applications, continuations, and/or divisionals.

- (e) "Party" means any party to these cases, including all of its officers, directors, employees, consultants, vendors, retained experts, and outside counsel and their support staffs.
- (f) "Producing Party" means any Party or non-party that discloses or produces any Discovery Material in these cases.
- (g) "Protected Material" means any Discovery Material that is designated as "CONFIDENTIAL," "CONFIDENTIAL ATTORNEYS' EYES ONLY," or "CONFIDENTIAL OUTSIDE ATTORNEYS' EYES ONLY SOURCE CODE," as provided for in this Order. Protected Material shall not include: (i) advertising materials that have been actually published or publicly disseminated; and (ii) materials that show on their face they have been disseminated to the public.
- (h) "Receiving Party" means any Party who receives Discovery Material from a Producing Party.
- (i) "Source Code" means computer code, scripts, assembly, binaries, object code, source code listings (e.g., file names and path structure), descriptions of source code (e.g., descriptions of declarations, functions, and parameters), object code listings and descriptions of object code, Hardware Description Language (HDL) or Register Transfer Level (RTL) files that describe the hardware design of any ASIC or other chip, and native Computer Aided Design (CAD) files that describe the hardware design of any component, the disclosure of which to another Party or non-party is likely to cause harm or competitive disadvantage to the Producing Party. To avoid any doubt, still images of CAD files are not Source Code and will not be subject to the

disclosure and review restrictions in Section 11. Still images of CAD files may be designated as "CONFIDENTIAL" or "CONFIDENTIAL - ATTORNEYS' EYES ONLY," as provided for in this Order.

3. **COMPUTATION OF TIME**

The computation of any period of time prescribed or allowed by this Order shall be governed by the provisions for computing time set forth in Federal Rules of Civil Procedure 6.

4. **SCOPE**

- (a) The protections conferred by this Order cover not only Discovery Material governed by this Order as addressed herein, but also any information copied or extracted therefrom, as well as all copies, excerpts, summaries, or compilations thereof, plus testimony, conversations, or presentations by Parties or their counsel in court or in other settings that might reveal Protected Material.
- (b) Nothing in this Protective Order shall prevent or restrict a Producing Party's own disclosure or use of its own Protected Material for any purpose, and nothing in this Order shall preclude any Producing Party from showing its Protected Material to an individual who prepared the Protected Material.
- (c) Nothing in this Order shall be construed to prejudice any Party's right to use any Protected Material with the consent of the Producing Party or by order of the Court.
- (d) This Order is without prejudice to the right of any Party to seek further or additional protection of any Discovery Material or to modify this Order in any way, including, without limitation, an order that certain matter not be produced at all.

(e) Any use of Protected Material at trial shall be governed by the orders of the trial judge and other applicable authorities. This Order does not govern the use of Protected Material at trial.

5. **DURATION**

Even after the termination of these cases, the confidentiality obligations imposed by this Order shall remain in effect until a Producing Party agrees otherwise in writing or a court order otherwise directs.

6. ACCESS TO AND USE OF PROTECTED MATERIAL

- (a) <u>Basic Principles</u>. All Protected Material shall be used solely for these cases or any related appellate proceedings, and not for any other purpose whatsoever, including without limitation, any other litigation, patent prosecution or acquisition, patent reexamination or reissue proceedings, or any business or competitive purpose or function. Protected Material shall not be distributed, disclosed, or made available to anyone except as expressly provided in this Order.
- Outside Counsel and any person associated with a Party who receives a Producing Party's material designated "CONFIDENTIAL ATTORNEYS' EYES ONLY" or "CONFIDENTIAL ATTORNEYS' EYES ONLY SOURCE CODE" under this Protective Order or who has access to, accesses, or otherwise learns of, in whole or in part, said material designated "CONFIDENTIAL ATTORNEYS' EYES ONLY" or "CONFIDENTIAL ATTORNEYS' EYES ONLY" or "CONFIDENTIAL ATTORNEYS' EYES ONLY SOURCE CODE" under this Protective Order shall not prepare, prosecute, supervise, advise, counsel, or assist in the preparation or prosecution of any patent application seeking a patent on behalf of the Receiving Party or its acquirer, successor, predecessor, or Affiliate in the field of non-invasive monitoring and/or consumer wearables (generally or as

described in any patent in suit) during the pendency of this Action and for two years after final termination of this action, including all appeals. To avoid any doubt, "prosecution" as used in this section does not include representing or advising a Party before a domestic or foreign agency in connection with a reissue, ex parte reexamination, covered business method review, inter partes review, opposition, cancelation, or similar proceeding; though in connection with any such foreign or domestic agency proceeding involving the patents-in-suit, any attorney who has access to, accesses, obtains, receives, or otherwise learns, in whole or in part, any other Party's "CONFIDENTIAL – ATTORNEYS' EYES ONLY" or "CONFIDENTIAL – ATTORNEYS' EYES ONLY – SOURCE CODE" shall not: (i) participate in the preparation, prosecution, supervision, advice, counsel, or assistance of any amended claims; (ii) reveal a Producing Party's Protected Material to any prosecuting reexamination counsel or agent; or (iii) use a Producing Party's Protected Material for any purpose not permitted by Section 1.

(c) <u>Secure Storage</u>, <u>No Export</u>. Protected Material must be stored and maintained by a Receiving Party at a location in the United States and in a secure manner that ensures that access is limited to the persons authorized under this Order. To ensure compliance with applicable United States Export Administration Regulations, Protected Material may not be exported outside the United States or released to any foreign national, even if within the United States. This applies to such information regardless of whether it is in the form of a stand-alone document or as an exhibit, attachment, or appendix to anything, including but not limited to briefs, reports, letters to counsel, discovery responses, or court filings—whether drafts or final versions. Foreign nationals shall not include the Parties' Outside Counsel who reside in the United States, agreed to be bound by the provisions of the Protective Order by signing a copy of Exhibit A, and who are identified in writing to the Producing Party. However, the Parties' Outside Counsel

may access briefs, reports, letters to counsel, discovery responses, and court filings (including drafts) that contain Protected Material for purposes of working on these cases while traveling temporarily outside the United States, exclusive of any exhibits or appendices that attach or substantially reproduce or summarize documents, data, or testimony that have been designated by any other party as Protected Material. The Parties will use their best efforts to minimize the amount of Protected Materials in those documents (including without limitation by redacting references to Protected Materials that are not necessary for the work performed outside of the United States) to help ensure the security of the Parties' Protected Materials. Also, if this case eventually requires depositions or experts located outside the United States, the parties will revisit this issue and attempt to agree about exporting specific materials to the extent necessary. The Parties agree that neither Party waives the right to seek amendment of this Protective Order by the Court, following a meet and confer, if other circumstances concerning exportation arise in this case.

- (d) <u>Legal Advice Based on Protected Material</u>. Nothing in this Protective Order shall be construed to prevent counsel from advising their clients with respect to these cases based in whole or in part upon Protected Materials, provided counsel does not disclose the Protected Material itself except as provided in this Order.
- (e) <u>Limitations</u>. Nothing in this Order shall restrict in any way a Producing Party's use or disclosure of its own Protected Material. Nothing in this Order shall restrict in any way the use or disclosure of Discovery Material by a Receiving Party: (i) that is or has become publicly known through no fault of the Receiving Party; (ii) that is lawfully acquired by or known to the Receiving Party independent of the Producing Party; (iii) previously produced, disclosed and/or provided by the Producing Party to the Receiving Party or a non-party without an

obligation of confidentiality and not by inadvertence or mistake; (iv) with the consent of the Producing Party; or (v) pursuant to order of the Court.

7. **DESIGNATING PROTECTED MATERIAL**

- (a) <u>Available Designations</u>. Any Producing Party may designate Discovery Material with any of the following designations, provided that it meets the requirements for such designations as provided for herein: "CONFIDENTIAL," "CONFIDENTIAL ATTORNEYS' EYES ONLY," or "CONFIDENTIAL OUTSIDE ATTORNEYS' EYES ONLY SOURCE CODE."
- (b) Written Discovery and Documents and Tangible Things. Written discovery, documents (which include "electronically stored information," as that phrase is used in Federal Rule of Procedure 34), and tangible things that meet the requirements for the confidentiality designations listed in Section 7(a) may be so designated by placing the appropriate designation on every page of the written material prior to production. For digital files being produced, the Producing Party may mark each viewable page or image with the appropriate designation, and mark the medium, container, and/or communication in which the digital files were contained. In the event that original documents are produced for inspection, the original documents shall be presumed "CONFIDENTIAL ATTORNEYS' EYES ONLY" during the inspection and re-designated, as appropriate during the copying process.
- (c) Native Files. Where electronic files and documents are produced in native electronic format, such electronic files and documents shall be designated for protection under this Order by appending to the file names or designators information indicating whether the file contains "CONFIDENTIAL," "CONFIDENTIAL ATTORNEYS' EYES ONLY," or "CONFIDENTIAL OUTSIDE ATTORNEYS' EYES ONLY SOURCE CODE," material, or

shall use any other reasonable method for so designating Protected Materials produced in electronic format. When electronic files or documents are printed for use at deposition, in a court proceeding, or for provision in printed form to an expert or consultant pre-approved pursuant to Section 12, the party printing the electronic files or documents shall affix a legend to the printed document corresponding to the designation of the Producing Party and including the production number and designation associated with the native file. The parties reserve the right to object to the use of any image format version of a document produced in native format to the extent any information has been altered.

(d) Depositions and Testimony. Parties or testifying persons or entities may designate depositions and other testimony with the appropriate designation by indicating on the record at the time the testimony is given or by sending written notice of how portions of the transcript of the testimony are designated within fifteen (15) days of receipt of the transcript of the testimony. If no indication on the record is made, all information disclosed during a deposition shall be deemed "CONFIDENTIAL - ATTORNEYS' EYES ONLY" until the time within which it may be appropriately designated as provided for herein has passed. Any Protected Material that is used in the taking of a deposition shall remain subject to the provisions of this Protective Order, along with the transcript pages of the deposition testimony dealing with such Protected Material. In such cases the court reporter shall be informed of this Protective Order and shall be required to operate in a manner consistent with this Protective Order. In the event the deposition is videotaped, the original and all copies of the videotape shall be marked by the video technician to indicate that the contents of the videotape are subject to this Protective Order, substantially along the lines of "This videotape contains confidential testimony used in this case and is not to be viewed or the contents thereof to be displayed or revealed except pursuant to the terms of the operative Protective Order in this matter or pursuant to written stipulation of the parties." Counsel for any Producing Party shall have the right to exclude from oral depositions, other than the deponent, deponent's counsel, the reporter and videographer (if any), any person who is not authorized by this Protective Order to receive or access Protected Material based on the designation of such Protected Material. Such right of exclusion shall be applicable only during periods of examination or testimony regarding such Protected Material.

8. <u>DISCOVERY MATERIAL DESIGNATED AS "CONFIDENTIAL"</u>

- (a) A Producing Party may designate Discovery Material as "CONFIDENTIAL" if it contains or reflects confidential, proprietary, and/or commercially sensitive information.
- (b) Unless otherwise ordered by the Court, Discovery Material designated as "CONFIDENTIAL" may be disclosed only to the following:
- (i) The Receiving Party's Outside Counsel, such counsel's immediate paralegals and staff, and any copying or clerical litigation support services working at the direction of such counsel, paralegals, and staff;
- (ii) Officers or employees of the Receiving Party, who may be, but need not be, in-house counsel for the Receiving Party, as well as their immediate paralegals and staff, to whom disclosure is reasonably necessary for this case, provided that each such person has agreed to be bound by the provisions of the Protective Order by signing a copy of Exhibit A;
- (iii) Any outside expert or consultant retained by the Receiving Party to assist in these cases, provided that disclosure is only to the extent necessary to perform such work; and provided that: (a) such expert or consultant has agreed to be bound by the provisions of the Protective Order by signing a copy of Exhibit A; (b) such expert or consultant is not a current

officer, director, or employee of a Party or of a competitor of a Party, nor anticipated at the time of retention to become an officer, director or employee of a Party or of a competitor of a Party; (c) such expert or consultant accesses the materials in the United States only, and does not transport them to or access them from any foreign jurisdiction (however, to avoid doubt, such expert or consultant may access reports (including drafts) that contain the materials for purposes of working on these cases while traveling temporarily outside the United States); and (d) no unresolved objections to such disclosure exist after proper notice has been given to all Parties as set forth in Section 12 below;

- (iv) Witnesses at depositions or hearings in these cases and the witnesses' counsel, provided however that the disclosure shall only be made to: (1) a witness who is an employee of the Producing Party, or identified on the document as an author, addressee, or recipient of the material in question, or if there are other indicia (such as from metadata, cover emails, or other records of distribution) that the witness has seen or had access to the document previously; or (2) a witness who has been designated to testify on behalf of the Producing Party on the subject matter of the material in question, provided however that the Protected Material shown to such a witness shall be limited to Protected Material of the Producing Party;
- (v) Court reporters, stenographers and videographers retained to record testimony taken in these cases, and their staff;
 - (vi) The Court, jury, and court personnel;
- (vii) Graphics, translation, design, trial consulting personnel, and/or other professional vendors, having first agreed to be bound by the provisions of the Protective Order by signing a copy of Exhibit A;

- (viii) Mock jurors having first agreed to be bound by the provisions of the Protective Order by signing a copy of Exhibit A.
- (ix) Any mediator who is assigned to hear these matters, and his or her staff, subject to their agreement to maintain confidentiality to the same degree as required by this Protective Order; and
- (x) Any other person with the prior written consent of the Producing Party.

9. <u>DISCOVERY MATERIAL DESIGNATED AS "CONFIDENTIAL – ATTORNEYS EYES ONLY"</u>

- (a) A Producing **Party** designate Discovery Material may as "CONFIDENTIAL - ATTORNEYS' EYES ONLY" if it contains or reflects information that is extremely confidential and/or sensitive in nature and the Producing Party reasonably believes that the disclosure of such Discovery Material is likely to cause harm or significant competitive disadvantage to the Producing Party. The Parties agree that the following information, if nonpublic, shall be presumed to merit the "CONFIDENTIAL - ATTORNEYS' EYES ONLY" designation: trade secrets, pricing information, financial data, sales information, sales or marketing forecasts or plans, business plans, sales or marketing strategy, product development information, engineering documents, testing documents, employee information, and other nonpublic information of similar competitive and business sensitivity.
- (b) Unless otherwise ordered by the Court, Discovery Material designated as "CONFIDENTIAL ATTORNEYS' EYES ONLY" may be disclosed only to:
- (i) The Receiving Party's Outside Counsel, provided that such Outside Counsel is not involved in competitive decision-making, as defined by *U.S. Steel v. United States*, 730 F.2d 1465, 1468 n.3 (Fed. Cir. 1984), on behalf of a Party or a competitor of a Party, and such

Outside Counsel's immediate paralegals and staff, and any copying or clerical litigation support services working at the direction of such counsel, paralegals, and staff;

assist in this action, provided that disclosure is only to the extent necessary to perform such work; and provided that: (a) such expert or consultant has agreed to be bound by the provisions of the Protective Order by signing a copy of Exhibit A; (b) such expert or consultant is not a current officer, director, or employee of a Party or of a competitor of a Party, nor anticipated at the time of retention to become an officer, director, or employee of a Party or of a competitor of a Party; (c) such expert or consultant is not involved in competitive decision-making, as defined by *U.S. Steel v. United States*, 730 F.2d 1465, 1468 n.3 (Fed. Cir. 1984), on behalf of a Party or a competitor of a Party; (d) such expert or consultant accesses the materials in the United States only, and does not transport them to or access them from any foreign jurisdiction (however, to avoid doubt, such expert or consultant may access reports (including drafts) that contain the materials for purposes of working on these cases while traveling temporarily outside the United States); and (e) no unresolved objections to such disclosure exist after proper notice has been given to all Parties as set forth in Section 12 below;

(iii) Witnesses at depositions or hearings in these cases and the witnesses' counsel, provided however that the disclosure shall only be made to: (1) a witness who is identified on the document as an author, addressee, or recipient of the material in question, or if there are other indicia (such as from testimony, metadata, cover emails, or other records of distribution) that the witness has previously seen or had access to the document or the information contained therein; or (2) a witness who has been designated to testify on behalf of the Producing Party on the subject matter of the material in question, provided however that

the Protected Material shown to such a witness shall be limited to Protected Material of the Producing Party;

- (iv) Court reporters, stenographers and videographers retained to record testimony taken in this action, and their staff;
 - (v) The Court, jury, and court personnel;
- (vi) Graphics, translation, design, trial consulting personnel, and/or other professional vendors, having first agreed to be bound by the provisions of the Protective Order by signing a copy of Exhibit A;
- (vii) Any mediator who is assigned to hear this matter, and his or her staff, subject to their agreement to maintain confidentiality to the same degree as required by this Protective Order; and
- (viii) Any other person with the prior written consent of the Producing Party.
- (c) In addition, a Party may disclose arguments and materials derived from Discovery Material designated as "CONFIDENTIAL ATTORNEYS' EYES ONLY" to mock jurors who have signed an undertaking or agreement agreeing not to publicly disclose Protected Material and to keep any information concerning Protected Material confidential. A Party may not disclose to mock jurors any original, as-produced materials or information (including, for example, documents, deposition testimony, or interrogatory responses) produced by another Party designated as "CONFIDENTIAL ATTORNEYS' EYES ONLY."

10. <u>DISCOVERY MATERIAL DESIGNATED AS "CONFIDENTIAL – OUTSIDE ATTORNEYS" EYES ONLY - SOURCE CODE"</u>

(a) To the extent production of Source Code becomes necessary to the prosecution or defense of the cases, a Producing Party may designate Source Code as

"CONFIDENTIAL – OUTSIDE ATTORNEYS' EYES ONLY - SOURCE CODE" if it comprises or includes confidential, proprietary, and/or trade secret Source Code.

- (b) Nothing in this Order shall be construed as a representation or admission that Source Code is properly discoverable in these cases, or to obligate any Party to produce any Source Code.
- (c) Unless otherwise ordered by the Court, Discovery Material designated as "CONFIDENTIAL OUTSIDE ATTORNEYS' EYES ONLY SOURCE CODE" shall be subject to the provisions set forth in Section 11 below, and may be disclosed, subject to Section 11 below, solely to:
- (i) The Receiving Party's Outside Counsel, provided that such Outside Counsel is not involved in competitive decision-making, as defined by *U.S. Steel v. United States*, 730 F.2d 1465, 1468 n.3 (Fed. Cir. 1984), on behalf of a Party or a competitor of a Party, and such Outside Counsel's immediate paralegals and staff, and any copying or clerical litigation support services working at the direction of such counsel, paralegals, and staff;
- assist in this action, provided that disclosure is only to the extent necessary to perform such work; and provided that: (a) such expert or consultant has agreed to be bound by the provisions of the Protective Order by signing a copy of Exhibit A; (b) such expert or consultant is not a current officer, director, or employee of a Party or of a competitor of a Party, nor anticipated at the time of retention to become an officer, director or employee of a Party or of a competitor of a Party; (c) such expert or consultant is not involved in competitive decision-making, as defined by *U.S. Steel v. United States*, 730 F.2d 1465, 1468 n.3 (Fed. Cir. 1984), on behalf of a Party or a competitor of a Party; (d) such expert or consultant accesses the materials in the United States only, and does not

transport them to or access them from any foreign jurisdiction; and (e) no unresolved objections to such disclosure exist after proper notice has been given to all Parties as set forth in Section 12 below:

- (iii) Witnesses at depositions or hearings in these cases and the witnesses' counsel, provided however that the disclosure shall only be made to: (1) a witness who is identified on the material as an author, addressee, or recipient of the material, or if there are indicia (such as from testimony, metadata, emails, or other records of distribution) that the witness has seen or had access to the materials previously; or (2) a witness who has been designated to testify on behalf of the Producing Party on the subject matter of the material in question, provided however that the Protected Material shown to such a witness shall be limited to Protected Material of the Producing Party;
- (iv) Court reporters, stenographers and videographers retained to record testimony taken in this action, and their staff;
 - (v) The Court, jury, and court personnel;
- (vi) Any mediator who is assigned to hear this matter, and his or her staff, subject to their agreement to maintain confidentiality to the same degree as required by this Protective Order; and
- (vii) Any other person with the prior written consent of the Producing Party.

11. <u>DISCLOSURE AND REVIEW OF SOURCE CODE</u>

(a) Any Source Code that is produced by Plaintiff will be made available for inspection at the San Francisco office of its outside counsel, Desmarais LLP, or any other location mutually agreed by the Parties. Any Source Code that is produced by Masimo will be made

available for inspection at the Orange County office of their outside counsel, Knobbe Martens Olsen & Bear LLP, or any other location mutually agreed by the Parties. Source Code will be made available for inspection between the hours of 8 a.m. and 6 p.m. on business days (i.e., weekdays that are not Federal holidays), although the Parties will be reasonable in accommodating reasonable requests to conduct inspections at other times.

- (b) Prior to the first inspection of any requested Source Code, the Receiving Party shall provide ten (10) days' notice of its intent to review the Source Code that has been made available by the Producing Party and, if known, the specific Source Code the Receiving Party intends to inspect. The Receiving Party shall provide seven (7) days' notice prior to any additional inspections.
- (c) Source Code that is designated "CONFIDENTIAL OUTSIDE ATTORNEYS' EYES ONLY SOURCE CODE" shall be produced for inspection and review subject to the following provisions, unless otherwise agreed by the Producing Party:
- the Receiving Party's Outside Counsel and/or experts in a secure room on a secured computer without Internet access or network access to other computers and on which all access ports have been disabled (except for one printer port), as necessary and appropriate to prevent and protect against any unauthorized copying, transmission, removal or other transfer of any Source Code outside or away from the computer on which the Source Code is provided for inspection (the "Source Code Computer" in the "Source Code Review Room"). The Producing Party shall install tools that are sufficient for viewing and searching the code produced, on the platform produced, if such tools exist and are presently used in the ordinary course of the Producing Party's business. The Receiving Party's Outside Counsel and/or experts may request that commercially available

software tools for viewing and searching Source Code be installed on the secured computer, provided, however, that (a) the Receiving Party possesses an appropriate license to such software tools; (b) the Producing Party approves such software tools (approvals will not be unreasonably denied); and (c) such other software tools are reasonably necessary for the Receiving Party to perform its review of the Source Code consistent with all of the protections herein. The Receiving Party must provide the Producing Party with the CD or DVD or other media containing such licensed software tool(s) at least seven (7) days in advance of the date upon which the Receiving Party wishes to have the additional software tools available for use on the Source Code Computer.

- (ii) No recordable media or recordable devices, including without limitation sound recorders, computers, cellular telephones, peripheral equipment, cameras, CDs, DVDs, or drives of any kind, shall be permitted into the Source Code Review Room.
- (iii) The Receiving Party's Outside Counsel and/or experts shall be entitled to take notes relating to the Source Code but may not copy the Source Code into the notes and may not take such notes electronically on the Source Code Computer itself or any other computer.
- (iv) The Producing Party may visually monitor the activities of the Receiving Party's representatives during any Source Code review, but only to ensure that no unauthorized electronic records of the Source Code and no information concerning the Source Code are being created or transmitted in any way.
- (v) No copies of all or any portion of the Source Code may leave the room in which the Source Code is inspected except as otherwise provided herein. Further, no other written or electronic record of the Source Code is permitted except as otherwise provided herein. The Producing Party shall make available a laser printer with commercially reasonable

printing speeds for on-site printing during inspection of the Source Code. The Receiving Party may print limited portions of the Source Code only when necessary to prepare court filings or pleadings or other papers (including a testifying expert's expert report). The Receiving Party may print the Source Code in 12-point font and with information necessary to later identify that Source Code, such as, but not limited to, a header or footer, that identifies the file name and directory path. Any printed portion that consists of more than fifteen (15) pages of a continuous block of Source Code shall be presumed to be excessive, and the burden shall be on the Receiving Party to demonstrate the need for such a printed copy. The Receiving Party may print out no more than 200 pages total without prior agreement from the Producing Party or order of the Court. The Receiving Party shall not print Source Code in order to review blocks of Source Code elsewhere in the first instance, i.e., as an alternative to reviewing that Source Code electronically on the Source Code Computer, as the Parties acknowledge and agree that the purpose of the protections herein would be frustrated by printing portions of code for review and analysis elsewhere, and that printing is permitted only when necessary to prepare court filings or pleadings or other papers (including a testifying expert's expert report). Upon printing any such portions of Source Code, the printed pages shall be collected by the Producing Party. The Producing Party shall Bates number, copy, and label "CONFIDENTIAL - OUTSIDE ATTORNEYS' EYES ONLY -SOURCE CODE" any pages printed by the Receiving Party. Within seven (7) days, the Producing Party shall either (i) provide one copy set of such pages to the Receiving Party or (ii) inform the Requesting Party that it objects that the printed portions are excessive and/or not done for a permitted purpose. If, after meeting and conferring, the Producing Party and the Receiving Party cannot resolve the objection, the Receiving Party shall be entitled to seek a Court resolution of whether the printed Source Code in question is narrowly tailored and was printed for a permitted purpose. The

burden shall be on the Receiving Party to demonstrate that such printed portions are no more than is reasonably necessary for a permitted purpose and not merely printed for the purposes of review and analysis elsewhere. The printed pages shall constitute part of the Source Code produced by the Producing Party in these cases.

(vi) All persons who will review a Producing Party's Source Code on behalf of a Receiving Party, including members of a Receiving Party's outside law firm, shall be identified in writing to the Producing Party at least five (5) days in advance of the first time that such person reviews such Source Code. Such identification shall be in addition to any other disclosure required under this Order. All persons viewing Source Code shall sign on each day they view Source Code a log that will include the names of persons who enter the locked room to view the Source Code and when they enter and depart. The Producing Party shall be entitled to a copy of the log upon one (1) day's advance notice to the Receiving Party.

(vii) Unless otherwise agreed in advance by the Parties in writing, following each day on which inspection is done under this Order, the Receiving Party's Outside Counsel and/or experts shall remove all notes, documents, and all other materials from the Source Code Review Room. The Producing Party shall not be responsible for any items left in the room following each inspection session, and the Receiving Party shall have no expectation of confidentiality for any items left in the room following each inspection session without a prior agreement to that effect. Proper identification of all authorized persons shall be provided prior to any access to the secure room or the computer containing Source Code. Proper identification requires showing, at a minimum, a photo identification card sanctioned by the government of any State of the United States, by the government of the United States, or by the nation state of the authorized person's current citizenship. Access to the secure room or the Source Code Computer

may be denied, at the discretion of the supplier, to any individual who fails to provide proper identification.

- (viii) Other than as provided above, the Receiving Party will not copy, remove, or otherwise transfer any Source Code from the Source Code Computer including, without limitation, copying, removing, or transferring the Source Code onto any recordable media or recordable device. The Receiving Party will not transmit any Source Code in any way from the Producing Party's facilities or the offices of its Outside Counsel of record.
- (ix) The Receiving Party's Outside Counsel of record may make no more than three (3) additional paper copies of any portions of the Source Code received from a Producing Party pursuant to Section 11(c)(v), not including copies attached to court filings or used at depositions, and shall maintain a log of all paper copies of the Source Code. The log shall include the names of the reviewers and/or recipients of paper copies and locations where the paper copies are stored. Upon one (1) day's advance notice to the Receiving Party by the Producing Party, the Receiving Party shall provide a copy of this log to the Producing Party.
- (x) The Receiving Party's Outside Counsel of record and any person receiving a copy of any Source Code shall maintain and store any paper copies of the Source Code at their offices in a manner that prevents duplication of or unauthorized access to the Source Code, including, without limitation, storing the Source Code in a locked room or cabinet at all times when it is not in use. No more than a total of fifteen (15) individuals identified by the Receiving Party shall have access to the printed portions of Source Code (except insofar as such code appears in any court filing or expert report).
- (xi) For depositions, the Receiving Party shall not bring copies of any printed Source Code. Rather, at least seven (7) days before the date of the deposition, the Receiving

Party shall notify the Producing Party about the specific portions of Source Code it wishes to use at the deposition, and the Producing Party shall bring printed copies of those portions to the deposition for use by the Receiving Party. The Producing Party shall also accommodate reasonable requests from the Receiving Party to make a Source Code Computer available at the deposition for use at the deposition. Copies of Source Code that are marked as deposition exhibits shall not be provided to the Court Reporter or attached to deposition transcripts; rather, the deposition record will identify the exhibit by its production numbers. All paper copies of Source Code brought to the deposition shall remain with the Producing Counsel's Outside Counsel for secure destruction in a timely manner following the deposition.

from the Producing Party, the Receiving Party may not create electronic images, or any other images, or make electronic copies, of the Source Code from any paper copy of Source Code for use in any manner (including by way of example only, the Receiving Party may not scan the Source Code to a PDF or photograph the code). Images or copies of Source Code shall not be included in correspondence between the Parties (references to production numbers shall be used instead), and shall be omitted from pleadings and other papers whenever possible. If a Party reasonably believes that it needs to submit a portion of Source Code as part of a filing with the Court, the Parties shall meet and confer as to how to make such a filing while protecting the confidentiality of the Source Code and such Source Code will not be filed absent agreement from the Producing Party that the confidentiality protections will be adequate. If a Producing Party agrees to produce an electronic copy of all or any portion of its Source Code or provide written permission to the Receiving Party that an electronic or any other copy needs to be made for a Court filing, access to the Receiving Party's submission, communication, and/or disclosure of electronic files or other materials

containing any portion of Source Code (paper or electronic) shall at all times be limited solely to individuals who are expressly authorized to view Source Code under the provisions of this Order. Where the Producing Party has provided the express written permission required under this provision for a Receiving Party to create electronic copies of Source Code, the Receiving Party shall maintain a log of all such electronic copies of any portion of Source Code in its possession or in the possession of its retained consultants, including the names of the reviewers and/or recipients of any such electronic copies, and the locations and manner in which the electronic copies are stored. Additionally, any such electronic copies must be labeled "CONFIDENTIAL - ATTORNEYS' EYES ONLY - SOURCE CODE" as provided for in this Order.

12. NOTICE OF DISCLOSURE

- (a) Prior to disclosing any Protected Material to any person described in Sections 8(b)(iii), 9(b)(ii), or 10(c)(ii) (referenced below as "Person"), the Party seeking to disclose such information shall provide the Producing Party with written notice that includes:
 - (i) the name of the Person;
 - (ii) an up-to-date curriculum vitae of the Person;
 - (iii) the present employer and title of the Person;
- (iv) an identification of all of the Person's past and current employment and consulting relationships in the past five years, including direct relationships and relationships through entities owned or controlled by the Person, including but not limited to an identification of any individual or entity with or for whom the person is employed or to whom the person provides consulting services relating to the design, development, operation, or patenting of technologies relating to non-invasive monitoring and/or consumer wearables (generally or as described in any patent in suit), or relating to the acquisition of intellectual property assets relating

to non-invasive monitoring and/or consumer wearables (generally or as described in any patent in suit);

- (v) an identification of all pending patent applications on which the Person is named as an inventor, in which the Person has any ownership interest, or as to which the Person has had or anticipates in the future any involvement in advising on, consulting on, preparing, prosecuting, drafting, editing, amending, or otherwise affecting the scope of the claims; and
- (vi) a list of the cases in which the Person has testified at deposition or trial within the last five (5) years.

Further, the Party seeking to disclose Protected Material shall provide such other information regarding the Person's professional activities reasonably requested by the Producing Party for it to evaluate whether good cause exists to object to the disclosure of Protected Material to the outside expert or consultant.

Party or Parties may object in writing to the Person for good cause. In the absence of an objection at the end of the ten (10) day period, the Person shall be deemed approved under this Protective Order. There shall be no disclosure of Protected Material to the Person prior to expiration of this ten (10) day period. If the Producing Party objects to disclosure to the Person within such ten (10) day period, the Parties shall meet and confer via telephone or in person within four (4) days following the objection and attempt in good faith to resolve the dispute on an informal basis. If the dispute is not resolved, the Party objecting to the disclosure will have four (4) days from the date of the meet and confer to seek relief from the Court and shall have the burden of proving the need for a protective order. If relief is not sought from the Court within that time, the objection

shall be deemed withdrawn. If relief is sought, designated materials shall not be disclosed to the Person in question until the Court resolves the objection.

- (c) For purposes of this section, "good cause" shall include an objectively reasonable concern that the Person will, advertently or inadvertently, use or disclose Discovery Material in a way or ways that are inconsistent with the provisions contained in this Order.
- (d) Prior to receiving any Protected Material under this Order, the Person must execute a copy of the "Agreement to Be Bound by Protective Order" (Exhibit A hereto) and serve it on all Parties.
- (e) An initial failure to object to a Person under this Section 12 shall not preclude the nonobjecting Party from later objecting to continued access by that Person for good cause. If an objection is made, the Parties shall meet and confer via telephone or in person within seven (7) days following the objection and attempt in good faith to resolve the dispute informally. If the dispute is not resolved, the Party objecting to the disclosure will have seven (7) days from the date of the meet and confer to seek relief from the Court. The designated Person may continue to have access to information that was provided to such Person prior to the date of the objection. If a later objection is made, no further Protected Material shall be disclosed to the Person until the Court resolves the matter or the Producing Party withdraws its objection. Notwithstanding the foregoing, if the Producing Party fails to move for a protective order within seven (7) business days after the meet and confer, further Protected Material may thereafter be provided to the Person.

13. CHALLENGING DESIGNATIONS OF PROTECTED MATERIAL

(a) A Party shall not be obligated to challenge the propriety of any designation of Discovery Material under this Order at the time the designation is made, and a failure to do so shall not preclude a subsequent challenge thereto.

- (b) Any challenge to a designation of Discovery Material under this Order shall be written, shall be served on Outside Counsel for the Producing Party, shall particularly identify the documents or information that the Receiving Party contends should be differently designated, and shall state the grounds for the objection. Thereafter, further protection of such material shall be resolved in accordance with the following procedures:
- (i) The objecting Party shall have the burden of conferring either in person, in writing, or by telephone with the Producing Party claiming protection (as well as any other interested party) in a good faith effort to resolve the dispute. The Producing Party shall have the burden of justifying the disputed designation;
- (ii) Failing agreement, the Receiving Party may bring a request or motion to the Court for a ruling that the Discovery Material in question is not entitled to the status and protection of the Producing Party's designation. The Parties' entry into this Order shall not preclude or prejudice either Party from arguing for or against any designation, establish any presumption that a particular designation is valid, or alter the burden of proof that would otherwise apply in a dispute over discovery or disclosure of information;
- (iii) Notwithstanding any challenge to a designation, the Discovery Material in question shall continue to be treated as designated under this Order until one of the following occurs: (a) the Party who designated the Discovery Material in question withdraws such designation in writing; or (b) the Court rules that the Discovery Material in question is not entitled to the designation.

14. **DATA SECURITY**

(a) The Receiving Party shall implement an information security management system ("ISMS") to safeguard Protected Materials, including reasonable and appropriate

administrative, physical, and technical safeguards, and network security and encryption technologies governed by written policies and procedures, which shall comply with at least one of the following standards: (a) the International Organization for Standardization's 27001 standard; (b) the National Institute of Standards and Technology's (NIST) 800-53 standard; (c) the Center for Internet Security's Critical Security Controls, Version 8; or (d) the most recently published version of another widely recognized industry or government cybersecurity framework. The Parties shall implement encryption of all Protected Materials in transit outside of network(s) covered by the Party's ISMS (and at rest, where reasonably practical). Moreover, the Parties agree not to access Protected Materials from public computers.

- (b) If the Receiving Party becomes aware of any unauthorized access, use, or disclosure of Protected Materials or devices containing Protected Materials ("Data Breach"), the Receiving Party shall promptly, and in no case later than 48 hours after learning of the Data Breach, notify the Producing Party in writing and fully cooperate with the Producing Party as may be reasonably necessary to (a) determine the source, extent, or methodology of such Data Breach, (b) recover or protect Protected Materials, and/or (c) to satisfy the Producing Party's legal, contractual, or other obligations. For the avoidance of doubt, notification obligations under this section arise when the Receiving Party both (a) learns of a Data Breach, and (b) learns that any of the Producing Party's Protected Materials are potentially subject to the Data Breach. The notification obligations set forth in this section do not run from the time the Data Breach itself.
- (c) If the Receiving Party is aware of a Data Breach, the Parties shall meet and confer in good faith regarding any adjustments that should be made to the discovery process and discovery schedule in these cases, potentially including but not limited to (1) additional security measures to protect Discovery Material; (2) a stay or extension of discovery pending investigation

of a Data Breach and/or implementation of additional security measures; and (3) a sworn assurance that Discovery Material will be handled in the future only by entities not impacted by the Data Breach. In the event of a Data Breach affecting Protected Material of the Designating Party, at the Designating Party's request, the Receiving Party within 10 business days shall provide a copy of its most recent ISMS policies and procedures that relate to the safeguarding of Protected Materials and that preceded the Data Breach. Further, the Receiving Party shall submit to reasonable discovery concerning the Data Breach.

15. SUBPOENAS OR COURT ORDERS

(a) If at any time Protected Material is subpoenaed by any court, arbitral, administrative, or legislative body, the Party to whom the subpoena or other request is directed shall immediately give prompt written notice thereof to every Party who has produced such Discovery Material and to its counsel and shall provide each such Party with an opportunity to move for a protective order regarding the production of Protected Materials implicated by the subpoena. The Producing Party must also notify in writing the party who caused the subpoena or order to issue in the other litigation that some or all of the material covered by the subpoena or order is subject to this Protective Order, and include a copy of this Protective Order. The parties agree to work together to allow the Producing Party to seek a protective order, after the filing of which the Party served with the subpoena or court order shall not produce any information designated in this action as "CONFIDENTIAL – ATTORNEYS EYES ONLY – SOURCE CODE" before a determination on the protective order by the court from which the subpoena or order issued, unless the Party has obtained the Producing Party's permission.

16. **FILING PROTECTED MATERIAL**

- (a) Absent written permission from the Producing Party or a court Order secured after appropriate notice to all interested persons, a Receiving Party may not file or disclose in the public record any Protected Material.
- (b) Any Party is authorized under District of Delaware Local Rule 5.1.3 to file under seal with the Court any brief, document or materials that are designated as Protected Material under this Order. However, nothing in this section shall in any way limit or detract from this Order's requirements as to Source Code.

17. INADVERTENT DISCLOSURE OF PRIVILEGED MATERIAL

production by a Party of Discovery Material subject to the attorney-client privilege, work-product protection, or any other applicable privilege or protection, despite the Producing Party's reasonable efforts to prescreen such Discovery Material prior to production, will not waive the applicable privilege and/or protection in any other federal or state proceeding if a request for return of such inadvertently produced Discovery Material is made promptly after the Producing Party learns of its inadvertent production. For example, the mere production of a privileged or work product protected document in this case as part of a production is not itself a waiver. Nothing in this Order shall be interpreted to require disclosure of irrelevant information or relevant information protected by the attorney-client privilege, work product doctrine, or any other applicable privilege or immunity. The parties do not waive any objections as to the production, discoverability, admissibility, or confidentiality of documents and ESI. Moreover, nothing in this Order shall be interpreted to require disclosure of information subject to privacy protections as set forth in law or

regulation, including information that may need to be produced from outside of the United States and/or may be subject to foreign laws.

- (b) Upon a request from any Producing Party who has inadvertently produced Discovery Material that it believes is privileged and/or protected, each Receiving Party shall immediately return such Protected Material or Discovery Material and all copies to the Producing Party, except for any pages containing privileged markings by the Receiving Party which shall instead be destroyed and certified as such by the Receiving Party to the Producing Party.
- (c) Nothing herein shall prevent the Receiving Party from preparing a record for its own use containing the date, author, addresses, and topic of the inadvertently produced Discovery Material and such other information as is reasonably necessary to identify the Discovery Material and describe its nature to the Court in any motion to compel production of the Discovery Material.

18. **INADVERTENT FAILURE TO DESIGNATE PROPERLY**

- Material as Protected Material with one of the designations provided for under this Order shall not waive any such designation provided that the Producing Party notifies all Receiving Parties that such Discovery Material is protected under one of the categories of this Order within ten (10) days of the Producing Party learning of the inadvertent failure to designate. The Producing Party shall reproduce the Protected Material with the correct confidentiality designation within five (5) days upon its notification to the Receiving Parties. Upon receiving the Protected Material with the correct confidentiality designation, the Receiving Parties shall return or securely destroy, at the Producing Party's option, all Discovery Material that was not designated properly.
- (b) A Receiving Party shall not be in breach of this Order for any use of such Discovery Material before the Receiving Party receives such notice that such Discovery Material

is protected under one of the categories of this Order, unless an objectively reasonable person would have realized that the Discovery Material should have been appropriately designated with a confidentiality designation under this Order. Once a Receiving Party has received notification of the correct confidentiality designation for the Protected Material with the correct confidentiality designation, the Receiving Party shall treat such Discovery Material (subject to the exception in Section 18(c) below) at the appropriately designated level pursuant to the terms of this Order.

(c) Notwithstanding the above, a subsequent designation of "CONFIDENTIAL," "CONFIDENTIAL – ATTORNEYS' EYES ONLY" or "CONFIDENTIAL – ATTORNEYS' EYES ONLY – SOURCE CODE" shall apply on a going forward basis and shall not disqualify anyone who reviewed "CONFIDENTIAL," "CONFIDENTIAL – ATTORNEYS' EYES ONLY" or "CONFIDENTIAL – ATTORNEYS' EYES ONLY – SOURCE CODE" materials while the materials were not marked "CONFIDENTIAL – ATTORNEYS' EYES ONLY" or "CONFIDENTIAL – ATTORNEYS' EYES ONLY – SOURCE CODE" from engaging in the activities set forth in Section 6(b).

19. INADVERTENT DISCLOSURE NOT AUTHORIZED BY ORDER

(a) In the event of a disclosure of any Discovery Material pursuant to this Order to any person or persons not authorized to receive such disclosure under this Protective Order, the Party responsible for having made such disclosure, and each Party with knowledge thereof, shall immediately notify counsel for the Producing Party whose Discovery Material has been disclosed and provide to such counsel all known relevant information concerning the nature and circumstances of the disclosure. The responsible disclosing Party shall also promptly take all reasonable measures to retrieve the improperly disclosed Discovery Material and to ensure that no further or greater unauthorized disclosure and/or use thereof is made.

(b) Unauthorized or inadvertent disclosure does not change the status of Discovery Material or waive the right to hold the disclosed document or information as Protected.

20. FINAL DISPOSITION

- (a) Not later than ninety (90) days after the Final Disposition of these cases, each Party shall return all Discovery Material of a Producing Party to the respective Outside Counsel of the Producing Party or destroy such Material, at the option of the Producing Party. For purposes of this Order, "Final Disposition" occurs after an order, mandate, or dismissal finally terminating these cases with prejudice, including all appeals.
- (b) All Parties that have received any such Discovery Material shall certify in writing that all such materials have been returned to the respective Outside Counsel of the Producing Party or destroyed. Notwithstanding the provisions for return of Discovery Material, Outside Counsel may retain one set of pleadings, correspondence and attorney and consultant work product (but not document productions) for archival purposes, but must return any pleadings, correspondence, and consultant work product that contain Source Code.

21. **MISCELLANEOUS**

- (a) <u>Right to Further Relief.</u> Nothing in this Order abridges the right of any person to seek its modification by the Court in the future. By stipulating to this Order, the Parties do not waive the right to argue that certain material may require additional or different confidentiality protections than those set forth herein.
- (b) <u>Termination of Matters and Retention of Jurisdiction</u>. The Parties agree that the terms of this Protective Order shall survive and remain in effect after the Final Determination of the above-captioned matters. The Court shall retain jurisdiction after Final Determination of these matters to hear and resolve any disputes arising out of this Protective Order.

- (c) <u>Successors</u>. This Order shall be binding upon the Parties hereto, their successors, and anyone, including law firms, who obtains access to Protected Material.
- (d) Right to Assert Other Objections. By stipulating to the entry of this Protective Order, no Party waives any right it otherwise would have to object to disclosing or producing any information or item. Similarly, no Party waives any right to object on any ground to use in evidence of any of the material covered by this Protective Order. This Order shall not constitute a waiver of the right of any Party to claim in these cases or otherwise that any Discovery Material, or any portion thereof, is privileged or otherwise non-discoverable, or is not admissible in evidence in these cases or any other proceeding.
- (e) <u>Modification by Court</u>. This Order is subject to further court order based upon public policy or other considerations, and the Court may modify this Order *sua sponte* in the interests of justice. The United States District Court for the District of Delaware is responsible for the interpretation and enforcement of this Order. All disputes concerning Protected Material, however designated, produced under the protection of this Order shall be resolved by the United States District Court for the District of Delaware.

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Dated: June 14, 2023

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Attorneys for Defendants Masimo Corporation and Sound United, LLC

IT IS SO ORDERED this <u>16th</u> day of June, 2023.

The Honorable Jennifer L. Hall

United States District Court Magistrate Judge

EXHIBIT A

Ι,	, acknowledge and declare that I have received a
copy of the Protective Orde	er ("Order") in Apple Inc. v. Masimo Corp. et al., United States
District Court, District of	Delaware, C.A. Nos. 22-1377-MN-JLH and 22-1378-MN-JLH.
Having read and understood	the terms of the Order, I agree to be bound by the terms of the
Order and consent to the juris	ediction of said Court for the purpose of any proceeding to enforce
the terms of the Order.	
Name of individual:	
Present occupation/jol	b description:
	Firm:
Address:	
Dated:	
	[Signature]

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